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The aim of the research program we are developing is to define molecular markers and their interaction with other risk factors as risk indicators for development of breast cancer among women with benign breast disease (BBD). Our specific aims are:

1. Estimate the incidence and time span of breast cancer development in a large cohort of African American and Caucasian women with biopsy-proven BBD;

2. Collect and archive in a specimen bank samples of benign breast disease lesions and breast cancer from women in this cohort;

3. Develop and test a questionnaire for collecting breast cancer risk factor information that will:
   a) allow the construction of an exposure index for lifetime exposure to sex hormones; and
   b) designed to be sensitive to the perceptions of African American as well as Caucasian women.

We are constructing a cohort of 4815 women with BBD between 1981-1994 who will be followed from 5-15 years and yield 248 women who will have developed invasive breast cancer. This work is building the foundation, in terms of a cohort, a specimen bank, a survey instrument, and a summary information index, for the conduct of molecular epidemiologic studies of breast cancer.

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FOREWORD

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Christine Cole Johnson 02/22/00

PI - Signature Date

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INTRODUCTION

The Specific Aims remain the same as the original proposal, which relate to laying part of the foundation for our long-term research objective. Our long-term goals are to define DNA markers and their interaction with other epidemiological characteristics in order to better describe risk indicators for the subsequent development of breast cancer. This work is being conducted among a cohort of women with benign breast disease (BBD), consisting of Caucasians and African Americans. We requested and obtained a no cost extension of our funds to complete the project in the fall of 1998, and wish to request another no cost extension this year through October of 2000. Our specific aims for this developmental work are:

1. to estimate the incidence and time span of breast cancer development in a large cohort of African American and Caucasian women with biopsy-proven BBD;

2. to collect and archive in a specimen bank samples of benign breast disease lesions and breast cancer from women in this cohort;

3. to develop and test a questionnaire for collecting breast cancer risk factor information that will:

   a) allow the construction of an exposure index for lifetime exposure to sex hormones; and

   b) designed to be sensitive to the perceptions of African American as well as Caucasian women.

This work is providing the infrastructure for a research program using the established cohort, biorepository and data collection instruments to provide further molecular discriminators of risk in addition to other correlates such as histologic parameters, estrogen and progesterone exposure, reproductive history, family history of breast

cancer, and various demographic characteristics. The important clinical and public health implications of this study include: 1) the ability to identify women with high risk lesions and/or personal characteristics who then can be targeted for follow up; 2) the ability to identify and reassure a larger population of women having lesions with no increased risk; and 3) the ability to correlate DNA markers, DNA ploidy and histology with hormonal and familial risk factors.

BODY

Women with benign breast lesions, particularly those with lesions classified as proliferative and especially as atypical hyperplasia, are at increased risk for subsequent development of breast cancer. The goal of the research program we have developed is to characterize selected DNA markers and their interaction with other epidemiologic risk factors, particularly exposure to estrogen, that can serve as risk indicators for subsequent development of breast cancer among two groups of women with benign breast disease (BBD), Caucasians and African Americans. This current application has accomplished preliminary work that has laid part of the foundation for our research program and will be generally applicable in the field of breast cancer epidemiology as well.

The information we are gaining from this work is being used in a study to evaluate, within the identified cohort and using a nested case-control design, histopathological, molecular, and personal characteristics, including estrogen related variables, and their interactions as risk factors for the development of breast cancer among African American and Caucasian women with biopsy proven BBD. The developed questionnaire will be useful in general in the conduct of epidemiological studies of breast cancer, especially those that include African American women.

Experimental Methods

1.0 **Specific Aim 1: Cohort Establishment and Follow-up**

1.1 Cohort Enrollment

Subjects for the cohort have been obtained from individuals who underwent breast biopsy at HFHS in Detroit, MI from 1981-1994. Each pathology report in the Department of Pathology patient files dated January 1981 through December 1994 was reviewed by a trained research assistant. (Between 28,000 and 66,000 reports are filed a year.) The research assistant completed the identification, pulling and copying of all breast related pathologic reports (n=10,034). Over the past year, Dr. Raju, co-investigator and pathologist, completed the screening review of the pathology reports and identifying the biopsies with a diagnosis of BBD. All reports were categorized into benign and malignant specimens, for which we developed a tracking form. Women with a concurrent or previous invasive carcinoma in the same or contralateral breast, or found to have a diagnosis of breast cancer within six months of the study biopsy, are excluded. They are identified by other pathology reports, the tumor registry, or other means, and are not included in the cohort as they cannot be considered wholly "disease free" (at risk) upon entry into the cohort. When multiple biopsies belonging to one individual are encountered, the first biopsy during the study time period is used, and the date of that biopsy is the time of study enrollment.

The number of eligible subjects with benign lesions was originally anticipated to be approximately 4815 (Table 1). This estimate was based on review of available material for 1981 and on data from the computerized data base available from 1988-1991. At HFHS, in accordance with departmental policy, all pathology material dating from 1981 has been saved. All cases of benign breast disease identified through this procedure have been enrolled in the cohort. All individuals enrolled as study subjects are being followed for occurrence of breast cancer.

Table 1. BBD Study Estimates, Follow up through 12-31-96

Year of BBD	No. BBD Samples	No. Excluded	No. Eligible Subjects	Years of Follow-up	Rate Applied per 100,000 Dx at HFH†	PY Follow-Up	Exp No. HFH Br. C	Total Cases ‡
1981	168	19	149	15	336	2235.24	7.5	10
1982	242	27	215	14	336	3005.16	10.1	13
1983	268	30	238	13	336	3090.31	10.4	14
1984	186	21	165	12	336	1979.78	6.7	9
1985	298	34	264	11	336	2907.59	9.8	13
1986	378	43	335	10	336	3352.86	11.3	15
1987	600*	68	532	9	551	4789.80	26.4	35
1988	821	93	728	8	551	5825.82	32.1	43
1989	740	84	656	7	551	4594.66	25.3	34
1990	840	95	745	6	551	4470.48	24.6	33
1991	887	100	787	5	551	3933.85	21.7	29
	5428	613	4815			40186	186	248

† Actual 1981 rate used for 1981-1986; actual average annual rates from 1988-93 used for 1987-1991.
‡ Based on the 1981 pilot cohort showing a third of cases of breast cancer diagnosed outside HFHS.
* Estimate, other years actual.

Table 2 below presents the actual number of subjects in the cohort by year and the number of cases ascertained thus far, although follow-up is not yet complete. From 1981-1994, index biopsy reports from 5254 women have been identified as benign and potentially eligible. We have completed initial follow-up attempts on all cohort members. Of those 3397 contacted, 91.9% provided information and 275 (8.1%) refused to participate. We are currently in the process of tracing the 1285 women we were unable to contact with out most recent address information.

Data bases have been developed and are continuing to be updated that include study ID, medical record number, pathology specimen number, and tracking form results, as well as information from other data sources (pathology classification, follow-up information, risk factor questionnaire, tumor registry).

Aim 1 of our study is to calculate the incidence of breast cancer in our cohort, stratifying by characteristics of our BBD subjects and the baseline pathology classifications. We will also evaluate time to diagnosis by initial pathology category. To date we have found 167 breast cancer cases. As stated earlier, our follow-up is not yet complete; however we have calculated updated crude incidence rates by year of BBD in the

table below based on data as it stood late last year. An abstract with incidence data from this study was presented at the American Association for Cancer Research meeting in April 1999, and updated data will be presented in April 2000.

Table 2. Calculation of crude incidence rates for breast cancer in the BBD study cohort, as of 1999 AACR submission

Year	No. eligible in BBD Cohort	Person-years of follow-up	No. breast cancer cases	Incidence rate/yr/100000
1981	229	3687	11	298.3
1982	263	4035	10	247.8
1983	265	3790	13	343.0
1984	234	3127	10	319.8
1985	347	4298	11	255.9
1986	431	4817	25	519.0
1987	504	5220	27	517.2
1988	436	4173	12	287.6
1989	426	3592	17	473.3
1990	376	2828	7	247.5
1991	372	2413	9	373.0
1992	457	2569	3	116.8
1993	389	1768	2	113.1
1994	525	1884	10	530.8
Total	5254	48201	167	346.5

For each potential benign breast specimen, a pathologist microscopically reviews all corresponding pathology slides and diagnostically records all lesions on a detailed Pathology Review Form (PRF) (see Appendix C). Our pathologists have reviewed a total of 2619 specimens (as of December 1999). An intra-rater reliability study has been incorporated into the pathology review, whereby a 10% sample from each cohort year is selected by the programmer for blinded rereview by the primary pathologist. Based on 23 rereviews, results indicate reliability to be well over 90%. Cases diagnosed with atypical hyperplasia are also reviewed by secondary pathologists for inter-rater reliability (50 cases have been completed to date).

1.2 Cohort Follow-up

The initial source for follow-up information has been the Henry Ford Health System (HFHS) tumor

registry. Many of the subjects who develop breast cancer, who continue to reside in metropolitan Detroit, return to HFHS for diagnosis and treatment. Information stored in the HFHS tumor registry includes basic demographics, in addition to occupation, family history of cancer, and a summary of concurrent and underlying medical conditions.

Secondly, we are locating and tracing each woman to interview her by telephone and inquire about breast cancer status (see form in appendix). A trained interviewer follows up and contacts cohort members to ascertain the occurrence of breast cancer and the willingness of cohort members to participate in a telephone interview at some later point in time. This task is not yet complete.

We have found that considerable information useful for locating study subjects is automated in our electronic medical record system, so we are utilizing that source initially to conduct follow-up. All women entered into the study and the next of kin of those known to be deceased, are being contacted through letter and follow-up phone call requesting information on cancer history and for a locator form for future contacts. Introductory letters have now been mailed for all years 1981- 1994 (n=5246). The names of those women remaining lost to follow-up after substantial tracing efforts are being linked with the statewide cancer and mortality registries. A request for this linkage is currently under review by the Michigan Department of Public Health. We have also recently learned of an internet-based tracing database that was developed for another study, and are attempting to link names with this resource, with substantial success thus far.

Subjects or their next of kin who have had a breast cancer diagnosed at a facility that is not affiliated with HFHS are being asked to sign a release document that gives us permission to obtain and review their hospital records to obtain specific information on the reported cancer and obtain pathological material. This component of the project is also still underway and not yet complete.

1.3 Sample Size and Analysis Plan

Based on our numbers to date, there will be data on approximately 5254 women diagnosed with benign breast disease during the years 1981 through 1994 in this study, which is somewhat fewer than we anticipated. The underestimate is mainly due to a larger percentage of multiple biopsies. Our person-years of follow-up are now estimated to be at 48,201. Our statistical power estimates are displayed below.

Expected 95% Exact Poisson Confidence Intervals

Incident Breast Cancer Cases

Per 1000 Person Years of Follow-up

Person Years of Follow-up	50	10	5	1
40,000	.048, .052	.009, .011	.004, .006	.0007, .0014
20,000	.047, .053	.009, .011	.004, .006	.0006, .0015
10,00	.046, .055	.008, .012	.004, .007	.0005, .0018
1,000	.037, .066	.005, .018	.002, .012	.00003, .0056

We will use Kaplan-Meier curves to describe time to detection of breast cancer adjusting for important covariates such as ethnicity and BBD histology.

2.0 Specific Aim 2: Identification and Archival of Breast Tissue Specimens

We have established a breast tissue biorepository for the pathological material collected from archived samples in this study. Dr. Worsham (Co-PI) is overseeing the breast tissue biorepository. The pathology archives have been and continue to be searched by the laboratory research assistant to retrieve slides and respective paraffin-embedded tissue blocks. When only blocks remain, the blocks are cut and new slides prepared for storage. We have completed slide review though 1993.

We recognize that this biorepository for many reasons will serve as an important resource for molecular studies of future relevant biomarkers. We have been able to appreciate with even greater clarity the limitations that are inherent with DNA amounts from small foci such as hyperplasia, atypical ductal hyperplasia and other preneoplastic lesions of small foci.

Finally, the HFHS Josephine Ford Cancer Center has made substantial progress in the last year (see report in Appendix) in the development of an organized system biorepository that will serve as a cultured cell bank and a DNA bank not only for breast cancer but other cancers as well. A grant requesting partial support for this tissue repository was submitted to NCI in November 1999 in response to an RFA.

3.0 Specific Aim 3: Development of a Risk Factor Questionnaire

3.1 Development of Sex Hormone Exposure Index

Numerous breast cancer risk factor studies have been conducted examining various characteristics that are surrogate measures of exposure to estrogen. However, in the past, selected characteristics were often analyzed in a univariate fashion, or controlling for only a few other estrogen-related variables. Further, the number of subjects required in a study to achieve optimal statistical power becomes daunting as the number of independent variables in an analysis increases and are used in a categorical fashion. We have developed, and now finalized a questionnaire, using a calendar approach as a memory prompt, to inquire extensively about factors that are associated with sex hormone exposure. We are also continuing to review the literature to obtain up-to-date information on data regarding physiologic levels of estrogen and progesterone related to reproductive characteristics and exogenous hormone exposures in order to derive weights for these characteristics

In the process of finalizing our variables to be collected, we have consulted with two physicians specializing in reproductive endocrinology, Ronald Strickler and Max Wisgerhof. Using our questionnaire, we hope to be able to assess cumulative hormonal exposure at various points of time in a woman's life in order to

examine whether cumulative exposure relative to age is important. There is reason to believe that the breast is most susceptible to carcinogenic influences at younger ages; DNA synthesis is higher in young individuals, and women under age 20 were at highest risk for radiation-induced breast cancer after atomic bomb exposure.

3.11 Variables to be Collected

We included on the data collection instrument questions about age at menarche, lifetime menstrual cycle pattern, menopausal history, dates and duration of pregnancies, duration of lactation, infertility, history of use of oral contraceptives, fertility drugs, estrogen replacement therapy, and height and weight history (see Appendix B for final version of questionnaire).

3.12 Development of Exposure Indices

Since we will not have actual hormone exposure data for individuals in potential retrospective studies (i.e. blood levels over time), exposure assessment in future studies will focus on the surrogate measures for estrogen and progesterone exposure as listed in the survey instrument and calendar. Importantly, we placed an emphasis on collecting the data in a manner that allows the assessment of changes over a woman's lifetime. We will assign estimated quantitative hormone exposure scores for different reproductive characteristics during various segments of a woman's life (for example, none/low, medium, and high categories) by relying on data in the literature and on the expertise and experience of the investigators and our consultants.

3.2 Design of a Risk Factor Questionnaire Sensitive to a Multi-Ethnic Population

Focus groups, which allow for group interaction and greater insight into the meaning of certain questions in specific populations, may be used to plan and design questionnaire items or to evaluate existing ones. Discussions during focus groups are a qualitative approach to learning about psychological and sociocultural

characteristics and processes in subgroups of the general population. Focus groups are typically composed of 7 to 10 participants who are usually homogenous in such characteristics as age, gender, race/ethnicity, and social characteristics.

In the summer of 1998, we held two focus groups for two purposes: to develop questions that are culturally tailored to African American women in the two age groups, and to examine the perceptions of the women toward components of existing questionnaires assessing estrogen exposure and other breast cancer risk factors. These perceptions were used to adapt our draft to make them better suited for use among African American women. The women's opinions regarding the cultural sensitivity and feasibility of existing questionnaire items related to estrogen risk factors was solicited. The first focus group (n=12) was held with African American women aged 18-150 years who were randomly selected from the Henry Ford Health System (HFHS) patient population and invited to participate in a two-hour focus group, while the second focus group (n=9) was held with African American women aged 50+ years who were recruited in a similar manner.

A sample set of focus group questions referring to a specific table in the breast cancer risk factor survey include: (a) Are the instructions on how to fill out the table clear to you?; (b) If not, how could they be made clearer?; (c) How would you feel if you were asked to complete this table?; (c) Are the words in the table clear to you?; (d) If not, which words would you use to describe these things?; and (e) How does the layout of the table look to you? The results of the focus group revealed several categories related to the survey design. These categories include the overall content of the survey, survey questions requiring calculations or detailed remembrances of past events, privacy and confidentiality issues, and the overall experience of completing the survey.

Each two-hour focus group was audiotaped and videotaped. Based on the comments the women generated during the focus group meetings, the questionnaires were revised. We now have transcripts from these focus groups (see Appendix), and presented information about this work at the 1999 AACR meeting and

the March 1999 workshop entitled the Multicultural Aspects of Breast Cancer Etiology (abstracts in Appendix D). A summary report of the focus groups is included as Appendix A.

3.3 Testing of RFQ

In the past year we piloted our penultimate version of the instrument (the Women's Health Study Risk Factor Questionnaire) on both African American and Caucasian women, as well as women who vary by age and socioeconomic status. The purpose of pilot testing the RFQ was tp evaluate the survey's content, layout, detail and readability. Female friends, family members and co-workers were asked to voluntarily complete the questionnaire through either self- or telephone interviewer administration. Thirty subjects received a questionnaire packet, through the U.S. mail or hand delivery, containing the survey, a Data Form to record demographic information, a Life Events Calendar to document important life events as an aid to survey completion, Continuation Pages for the Pregnancy and Family History sections, a Body Picture diagram to assess body image, and an Evaluation Form for the subject to write their impression of the questionnaire. Seven surveys were self-administered while ten were completed with the assistance of a telephone interviewer. Comments on the materials, recorded on either the form itself or the evaluation form, were compiled. Based on the feedback from the women, the survey was considered clearly written and easy to understand; the layout was noted as good but a few found it lengthy or somewhat complex; the level of detail and ability to recall was mostly considered difficult but most subjects were able to complete the survey in its entirety; and the survey package, in its entirety, was thought to be good and helpful. The questionnaire took approximately one hour to complete. Detailed data on these pilot results are included in Appendix A.

Comments and suggestions specific to certain sections were assessed and alterations made: consolidation of questions under the Pregnancy section, simplification of the Menstruation and Menopausal History section,

reconstruction of the Household and Exercise Physical Activity sections, and inclusion of half-sibling data in the Family History Section. Other changes from the investigator's discernment included simplification of the wording, text spacing, section title revisions, and additional answer choices and skip pattern directions. Based on this pilot study and cost concerns, for a full scale implementation we would recommend mailing the survey to subjects for self-administration with the option of completing the survey with a telephone interviewer if requested. The final version is included in Appendix B.

Because of the prolonged length of time it took to complete the pilot, we have not been able to conduct any reliability studies. In the beginning of 2000, we are set to embark on this effort. Rather than surveying women from our databases, we now plan on conducting the reliability studies on a sample from the established cohort in order to increase efficiency. We will do this by administering selected sections of the questionnaire using combinations of the two different methods to the same women with a four-month interval between administrations. Sections from each type of questionnaire (self and phone) will be re-administered by the same interviewer 4 months after the initial interview. We hope that the intervening four months will be a long enough period to preclude retained memory of previous responses to the questionnaire. Variables that are not time-sensitive will be analyzed for comparability, taking into consideration changes that may have occurred over 4 months.

We will also assess intra- and inter-interviewer reliability for the interviewer-administered version of the instrument. Two different interviewers will administer identical sections from the same questionnaire to the same subject four months apart. Again, comparisons will be made between non-time-sensitive variables.

Each of the reliability assessments will be made in the subgroups of Caucasian women and African American women, as well as pre-menopausal and post-menopausal women.

3.5 Use of RFQ Results

Based on the results from the reliability studies, further recommendations will be made as to whether different data collection modalities may be employed in future studies using these instruments.

4.0 Spin-off benefits of the DoD funding

As a spin-off to this work, we linked all the breast cancer cases in the HFHS tumor registry with the Detroit SEER registry to obtain survival data. We analyzed these data with a focus on explaining the difference in survival between a subset of African American (AA) and European American (EA) women belong to our system HMO. Screening, diagnosis, treatment and follow-up patterns for this population are based on standard practices within the medical group, with mammography as a covered benefit. We abstracted data on cases of breast cancer diagnosed between 1986-1996 (N=886) and followed these cases for survival through April 1997 (N=137 deaths). Many studies have shown that AA women with breast cancer have poorer survival than EA women. After adjustments for socioeconomic variables, survival differences between blacks and whites are generally diminished, but remain, and may be due to residual differences in access to health care or biologic or behavioral differences. In our study, AA women were diagnosed at a later stage when compared with EA women. Five-year survival was 77% for AAs and 84% for EAs. Using a Cox regression model, the crude hazard for AAs relative to EAs was 1.6 (95% confidence interval (CI) 1,1, 2.2). Adjusting only for stage of disease at diagnosis, the hazard ratio was 1.3 (95% CI 0.9, 1.9). Adjusting only for sociodemographics (age, marital status and income), the hazard ratio was 1.2 (95% CI 0.8, 1.9). After adjusting for age, income, marital status and stage, the hazard ratio was 1.0 (95% CI 0.7, 1.5). Thus, adjustments taking into consideration differences in stage, sociodemographic and tumor-specific prognostic factors eliminated the effect of race on survival among AA and EA women with breast cancer. In Appendix E is a paper describing these results which was recently published in the *Journal of the National Cancer Institute*. We also examined treatment

differences between these groups and found no material differences (published in the Annals of Surgery in 1999).

Over the summer, the research assistant who has been working on this project, together with some students working with us, obtained the medical records of the women in the breast cancer survival study to abstract information regarding the use of screening mammography, in an attempt to explain the difference between stage at diagnosis. Even within a staff model HMO where there are strong organizational and physician incentives to promote mammography, we found a substantial difference between ethnic groups in the occurrence of a screen before breast cancer diagnosis. However, when adjusting for mammography, we still found a stage difference by race among younger women, with African Americans having a higher stage at diagnosis. These results have been accepted to be presented at the AACR 2000 meeting (Appendix D).

These studies used several processes that will be useful in future breast cancer research. This study demonstrated that our administrative billing data can be used effectively to update the HFMG tumor registry. It served to refine statistical methods that will be employed in later data analyses. For example, we considered the possibility that our method of updating the tumor registry's "date last known alive" with visit data would bias our estimates of survival, if one ethnic group were more likely to have contact with our physicians following diagnosis. Therefore, we conducted the analysis twice: first, only tumor registry follow-up dates were included; second, we used the updated data. Only negligible differences between the two approaches were found, justifying analyses with the updated data.

The investigators/consultants/staff on this proposal have also reported results related to breast cancer in other manuscripts or at national meetings, as follows:

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Ulckickas Yood M, Johnson CC, Blount A, Abrams J, Wolman E, McCarthy BD, **Raju U, Nathanson DS, Worsham M, Wolman SR**. Lack of racial differences in breast cancer survival in a managed care population. J Natl Cancer Inst 1999, 91 (17):1487-1491.

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Blount AC, Raju U, Abrams J, Jankowski M, Nathanson SD, Wolman SR, Worsham MJ, Johnson CC. Breast cancer incidence among a cohort of women with benign breast disease. American Association for Cancer Research, 2000.

Johnson CC, Bawle U, Ulcickas Yood ME. Ethnicity, stage of detection of breast cancer and screening mammography in a health maintenance organization. Accepted, the HMO Research Network, 2000.

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Worsham MJ, Wolman SR, Raju U, Barnabas N, Nathanson DN, Pals G: evaluation of the *atm* locus as a contributing factor in development/progression of *brca1* germline-mutated tumors. Association for Molecular Pathology, San Diego

Worsham MJ, Wolman SR, Raju U, Barnabas N, Nathanson DN, Pals G, **Zarbo RJ**: Evaluation of *BRCA1* antibodies as a screening tool for germline *BRCA1* mutations. Association for Molecular Pathology, San Diego

Ali R, Wiesner G, Kaisi N, Badin R, Pals G, **Worsham MJ**. Loss of heterozygosity (LOH) and microsatellite instability (MSI) of the BRCA1 locus in Arabic women with breast cancer: 4th Annual Multidisciplinary Symposium on Breast Disease, Amelia Island February 11-14, 1999

Pals G, K. Pindolia K, **Worsham MJ**. Mutation detection in BRCA1 using real time PCR and melting curve analyses. 49th American Society Human Genetics Meeting, San Francisco, October 19-23, 1999

Pals G, Young C, Mao H, Pindolia K, **Worsham MJ**. Single cell mutation detection in *BRCA1* utilizing real time PCR and melting curve analyses. Association of Molecular Pathology, Nov. 1999.

Worsham MJ, Ali R, Pals G: Ethnic differences in breast cancer susceptibility. Second Asian Conference in Breast Cancer, Tianjin, China, September 1-2, 1999.

Worsham MJ, Johnson CC, Raju U, Abrams J, Blount A, Wolman SR. Benign breast disease (BBD) and risk of breast cancer (BC): Incidence rates for BC and intra observer reliability in classifying BBD Lesions. Second World Breast Cancer Conference, Ottawa, Canada, July 25-30, 1999, 49th American Society Human Genetics Meeting, San Francisco, October 19-23, 1999.

Worsham MJ, Macoviak P, Patel N, **Zarbo RJ**. Status of the Her2/neu gene testing in breast cancer: FISH versus IHC: A study of 165 patients. Association of Molecular Pathology, Nov. 1999

Students who have worked on the project:

Ulke Bawle, masters student, University of Michigan, June 1997-May 1999, doctoral student, Columbia, Sept 1999- present.

Robert Coates, University of Michigan School of Public Health, Wayne State University Medical School, masters and medical student June 1998 through the present

Marianne Ulcickas-Yood, Boston University, doctoral student, fall 1997 through June 1998.

Conclusions

As was reported last year, progress was slower than planned, due to the fact that the hard copy pathology report review (now complete) and the pathology classification (now complete) took longer than anticipated, which backed up all study processes. Therefore, we did not use as much interviewing and follow-up time,

resulting in funds left over last year and this year. These funds, designated for the PI, interviewer research time, and travel to scientific meetings including the DoD breast cancer meeting in June 2000, will be used to finish the project in the next year. To complete this study's Specific Aims, we plan to accomplish the following tasks within this final extension of funding:

-Complete the storage (1994 slides and blocks) and microscopic review (1988-1994) of pathology material

-Complete tracing of cohort for ascertainment of breast cancer

-Evaluate the reliability of the Risk Factor Questionnaire instrument

-Continue to write up results for publication

Our results will yield a well-documented cohort, biorepository, and data base from which to generate study ideas. We will also have a risk factor questionnaire to be used in studies evaluating reproductive and medication related variables in women's health studies, especially epidemiologic studies of breast cancer.

APPENDIX A.

Focus Group Reports

Pilot Study Results

Developing A Culturally Appropriate Breast Cancer Risk Factor Survey for African American Women

Ford, ME, Hill DD, Worsham MJ, and Johnson CC.
Henry Ford Health System
Josephine Ford Cancer Center and
Resource Center for African American Aging Research

ABSTRACT

The purpose of this study was to develop a culturally appropriate breast cancer risk factor survey. Guided focus groups were conducted using items compiled from standardized surveys on breast cancer risk factors. The first focus group (n=12) was held with African American women aged 18-50 years randomly selected from the Henry Ford Health System patient population. A second focus group was held with nine randomly selected African American women aged 50+ years. Each two-hour focus group was videotaped. The women in the younger age group stated that the rationale for the item on race/ethnicity was not clear, the relevance between parent□s country of origin and breast cancer risk was not clear, and that it was difficult to remember the number of menstrual periods they had had in previous decades. In the younger age group, breast cancer risk factors cited included heredity, smoking, underwire brassieres, chemical exposure, breast density, weight, drug use, and lack of estrogen exposure. The women in the older age group stated that in the past, their doctors did not name their medications or describe the full extent of their medical conditions. The meaning of several terms, such as demographics, was not clear, and family medical history was often unknown. In the older age group, breast cancer risk factors cited included heredity, hormone replacement therapy, diet, lack of breast self-exams and mammography, and estrogen exposure. Women in both age groups stated that it was difficult to recall previous average weight, alcohol consumption, and level of physical activity, and that the sports listed were not culturally appropriate. The results show that questionnaire items developed in the general population may not be appropriate for African American women, and that education about breast cancer risk factors is needed for this population.

RATIONALE FOR ASSESSING THE BREAST CANCER RISK FACTOR SURVEY FOR ITS LEVEL OF CULTURAL APPROPRIATENESS

- Practice guidelines and public policies are based upon research using existing measurement instruments to assess physical health and mental health outcomes.

- However, age and racial/ethnic group differences may exist in the structure and measurement of these outcomes.{1226,1227,1231,1202,1207,1224,1210,1216}

- Each racial/ethnic group has its own set of cultural characteristics.

- The factor structures of health measures may differ across age and racial/ethnic groups.

- Instruments tested in one population with high reliabilities may show low reliability when tested in another population.

- Within specific age and racial/ethnic groups, there is a need to examine the reliability and validity of measurement instruments, including those "validated" in the general population.

- Even instruments used as "gold standards" may still need to be assessed for specific population groups.

- It Is Important:

    1. Not to assume that the meaning of terms is the same across age and racial/ethnic groups.
    2. To understand the cultural context in which responses to questionnaire items are made. Understanding the cultural context can aid in the interpretation of data.

RATIONALE FOR CONDUCTING FOCUS GROUPS

- Culturally appropriate measurement instruments can be developed through the use of focus groups.
- Focus group research can be a rich source of information.
- Data are collected from a homogeneous group of individuals using a predetermined, structured sequence of questions in a focused discussion (Krueger 1988).
- Qualitative as well as quantitative data may be acquired (Kohler et al. 1993).
- An advantage of incorporating both qualitative and quantitative components in the focus group sessions is the ability to analyze the degree of congruence between the two types of evaluation (Kohler et al. 1993).

- Focus Groups:

1. Can be conducted with individuals representative of the population(s) that will complete the survey.
2. Can help develop/modify questions that have meaning for each population.
3. Allow for an in-depth exploration of the knowledge, attitudes and beliefs of specific cultural groups. It is difficult to obtain as wide an array of information from a survey.

GOALS OF THE PRESENT STUDY

- In the present study, focus groups were used for two purposes:
  1. To elicit feedback from two age-specific groups of African American women regarding an existing breast cancer risk factor survey.
  2. To obtain detailed information about the perception of breast cancer risk factors among the two groups of women aged 18-50 years and 50+ years.

METHODS

- A 20-page moderator's guide based on the existing breast cancer risk factor survey was developed.
- The Henry Ford Health System (HFHS) Corporate Data Store was used to randomly identify patients meeting the following criteria:
    1. African American
    2. Women
    3. Aged 18-50 years (focus group one) and aged 50+ years (focus group two)
    4. Visit made to HFHS in the last six months

- From this listing of potential participants, women were randomly selected to be called by telephone and invited to participate in a focus group.
- A short eligibility screener was conducted during the invitational call. In addition, the $40 honorarium was described.
- Eligible and interested women were sent a written confirmation of their focus group date, time, and location. (Transportation to the focus groups was not provided.)
- The women received a reminder call the night before their scheduled focus group session.

METHODS (cont'd)

- In conducting the focus groups, the following procedures were used:
  1. During each focus group, the moderator, assistant, and recorder were African American women under 40 years of age.
  2. The two-hour focus groups were videotaped and audiotaped.
  3. Prior to each focus group, participants signed a consent form and received a packet containing a nameplate (for identification of participants to the moderator), a copy of the survey to be evaluated, and a body image pictograph.
  4. The purpose of the focus group was explained, and participants were encouraged to freely voice their opinions.
  5. Confidentiality ground rules were laid.
  6. The focus groups began with a icebreaker.
  7. Then, the moderator began asking questions. A sample set of questions referring to a specific table in the breast cancer risk factor survey include:
     (a) Are the instructions on how to fill out the table clear to you?
     (b) If not, how could they be made clearer?
     (c) How would you feel if you were asked to complete this table?
     (d) Are the words in the table clear to you?
     (e) If not, which words would you use to describe these things?
     (f) How does the layout of the table look to you?
  8. Following the focus groups, participants signed a receipt and were given a $40 honorarium.

PRELIMINARY RESULTS

In the younger age group, participants stated that:

- The rationale for the item on race/ethnicity was not clear.
- The relevance between parent's county of origin and breast cancer risk was not clear.
- It was difficult to remember the number of menstrual periods they had had in previous decades.

In the older age group, participants stated that:

- In the past, their doctors did not name their medications.
- In the past, their doctors did not describe to them the full extent of their medical conditions.
- The meaning of several terms, such as "demographics", was not clear.
- Family medical history was often unknown.

PRELIMINARY RESULTS (cont'd)

Table 1
Comments Based on the Breast Cancer Risk Factor Survey

Younger Age Group (n=12)	Older Age Group (n=9)
• Rationale for race/ethnicity item was not clear. • Relevance of parent's country of origin was not clear. • Difficult to remember details about past menstrual periods.	• In the past, doctors did not name their medications. • In the past, doctors did not describe their medical conditions. • Meaning of several terms was not clear • Family medical history was often unknown.

PRELIMINARY RESULTS (cont'd)

Breast cancer risk factors cited by women in the younger age group included:

- Heredity
- Smoking
- Wearing underwire brassieres
- Chemical exposure
- Breast density
- Weight
- Drug use
- Lack of estrogen exposure

Breast cancer risk factors cited by women in the older age group included:

- Heredity
- Hormone replacement therapy
- Diet
- Lack of breast self-exams
- Lack of mammography
- Estrogen exposure

Table 2
Breast Cancer Risk Factors Cited by Focus Group Members

Younger Age Group (n=12)	Older Age Group (n=9)
• Heredity • Smoking • Wearing underwire brassieres • Chemical exposure • Breast density • Weight • Drug use • Lack of estrogen exposure	• Heredity • Hormone replacement therapy • Diet • Lack of breast self-exams • Lack of mammography • Estrogen exposure

PRELIMINARY RESULTS (cont'd)

In both age groups, participants stated that it was difficult to recall previous:

- Average weight
- Alcohol consumption
- Level of physical activity

Participants in both age groups also noted that the sports listed (such as tennis) were not culturally appropriate.

FUTURE DIRECTIONS

Congruent with the approach used by Kohler et al. (1993), the analysis of the data generated by the focus group in conjunction with the knowledge and experience of the study investigators will be used to guide the development of a revised breast cancer risk factor survey.

SUMMARY

Clinical decision-making algorithms and public policies are typically based on the results of research using measurement instruments. These algorithms and policies affect the manner in which health care is provided. Therefore, it is important to assess the cultural appropriateness of measurement instruments for use with specific populations. The results of this research show that breast cancer risk factor questionnaire items developed in the general population may not be appropriate for use with African American women, and that education about breast cancer risk factors is needed for members of this population. In addition, generational differences in response to questionnaire items were seen, indicating that these differences will also need to be taken into account when revising the survey.

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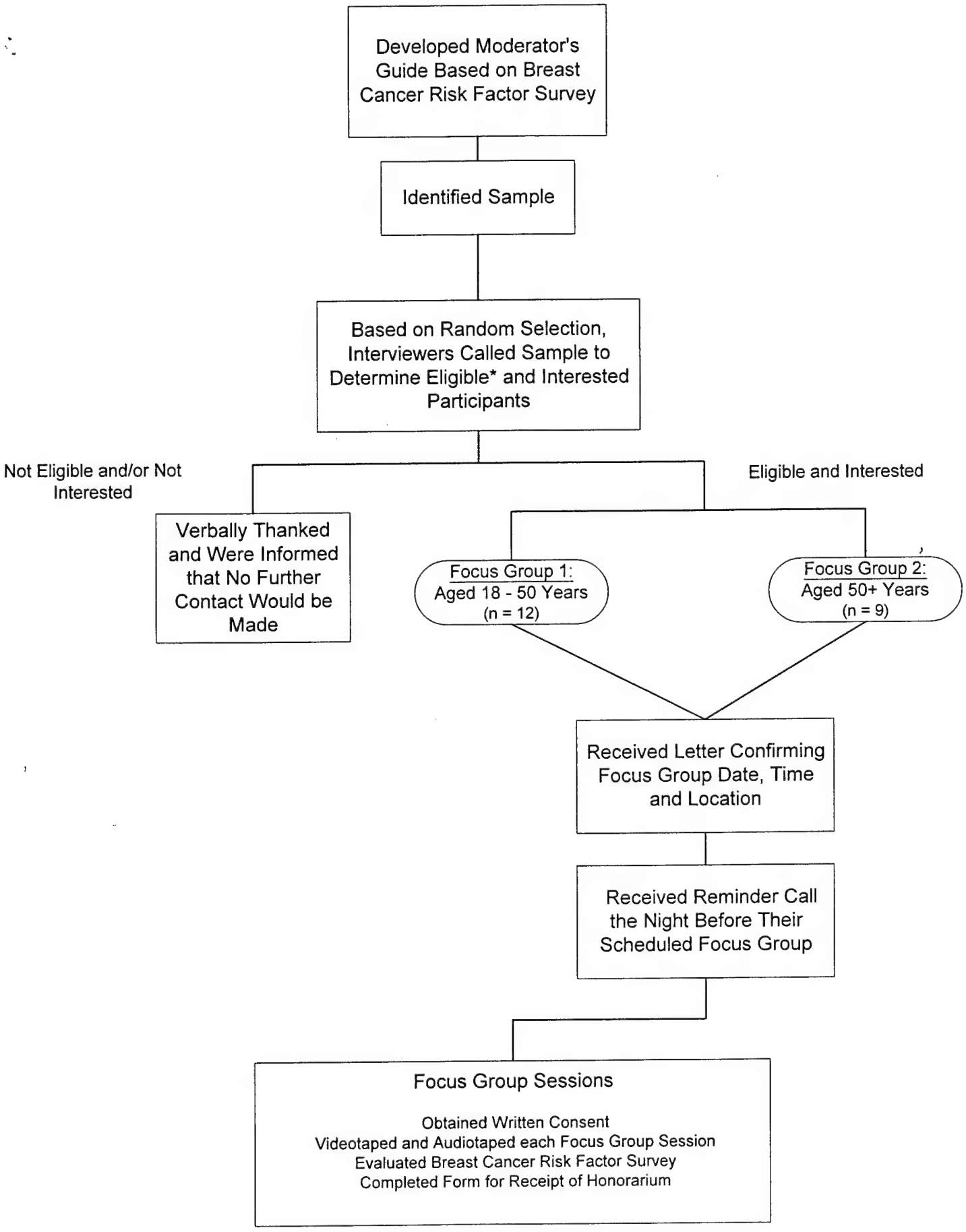

*confirmed age, race/ethnicity, and gender

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USING FOCUS GROUPS IN BREAST CANCER RESEARCH

Ford ME, Hill DD, Worsham JM, Johnson CC, Wolman S.
Henry Ford Health System
Resource Center on African American Aging Research and
Josephine Ford Cancer Center

ABSTRACT

Objective: To describe the results of two age-specific guided focus groups held with African American women to evaluate a breast cancer risk factor survey.

Methodology: A health system patient database was used to identify African American women aged 18-50 years (focus group one) and aged 50+ years (focus group two). From these listings, fifteen women were randomly selected, called and invited to each focus group. Eligible and interested women received a mailed confirmation of their focus group and a reminder call. Each two-hour focus group was videotaped.

Results: The women in the younger age group (n=12) stated that the rationale for the item on race/ethnicity was not clear, the relevance between parent's country of origin and breast cancer risk was not clear, and that it was difficult to remember the number of menstrual periods they had had in previous decades. The women in the older age group (n=9) stated that in the past, their doctors did not name their medications. The meaning of several terms, such as "demographics", was not clear, and family medical history was often unknown. Women in both age groups stated that it was difficult to recall previous average weight, alcohol consumption, level of physical activity, and that the sports listed were not culturally appropriate.

Conclusion: The results show that questionnaire items developed in the general population may not be appropriate for African American women.

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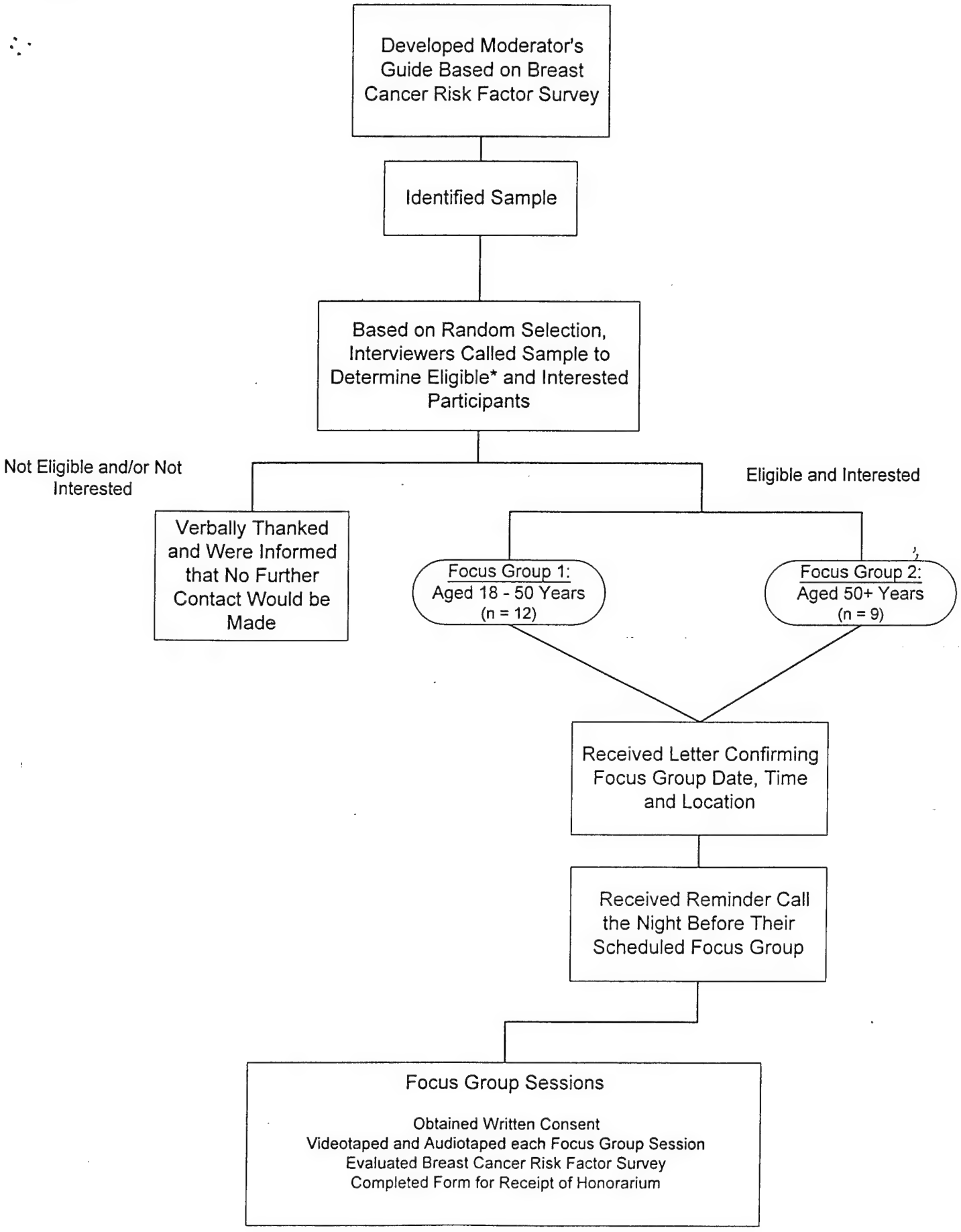

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BENIGN BREAST DISEASE STUDY

Risk Factor Questionnaire Pilot Results

I. Completed Surveys

To conduct the pilot testing of the risk factor questionnaire, female friends, family members and co-workers were asked to complete the survey and corresponding evaluation form to provide feedback to the layout, content, detail and clarity of the survey. Women had the choice of completing the survey through either telephone- or self-administration.

The table below represents the number of women who voluntarily completed the survey through either telephone or self-administration stratified by race and age.

	< 50 White	**≥ 50 White**	**< 50 Black**	**≥ 50 Black**	**Total**
Phone	3	0	5	2	10
Self	1	4	0	2	7
Total	4	4	5	4	17

II. Evaluation Form Comments

The responses to each evaluation form question are listed below, grouped by similarity and listed from positive to negative expressions. The administration type, age and racial category of the respondent is noted in *( )* after each comment *(P: Phone; S: Self; W: White; B: Black)*. Thirteen women completed the evaluation form.

1. Were the questions in the survey clearly written and easy to understand? Please explain.

Yes *(P: < 50 W; P: < 50 W; P: < 50 B; P: < 50 B; P: ≥ 50 B; S: ≥ 50 W; S: ≥ 50 W).*
Yes, they were very specific *(S: ≥ 50 W).*
Yes, for the most part *(P: < 50 B; P: < 50 W).*

Some of them, I needed help. All in all, it wasn't too bad *(P: ≥ 50 B).*
Fairly easy to understand *(S: ≥ 50 B).*

Some questions were too wordy for example: pages 24 and 26 *(P: < 50 B).*

2. How did you find the format and layout of the questionnaire?

Very good. It moved along at a quick pace *(S: ≥ 50 W)*.
Pretty good. It was helpful for me to have to go over it together *(P: < 50 W)*.

Format and layout are good *(S: ≥ 50 W)*.
Good *(P: < 50 W)*.
Very nice *(P: ≥ 50 B)*.
Fine *(P: < 50 W; S: ≥ 50 W)*.
It was fine *(P: < 50 B)*.
Okay *(P: ≥ 50 B)*.
Clear *(P: < 50 B)*.

Somewhat complex *(P: < 50 B)*.

Very lengthy – lots of repeated information *(S: ≥ 50 B)*.
Again, too wordy, pages 24 and 26 *(P: < 50 B)*.

3. How did you find the questions in terms of the level of detail, ability to recall, etc.?

Good *(P: < 50 B)*.
Very detailed, its simple *(P: ≥ 50 B)*.
It was easier to recall in groups *(P: < 50 W)*.
Not bad *(P: ≥ 50 B)*.

Very detailed questions, my ability to recall past events was just a little difficult *(P: < 50 B)*.

Very difficult *(S: ≥ 50 W)*.
The questions about physical activity are difficult to answer because of difficulty to recall *(S: ≥ 50 W)*.
Very difficult in some areas, such as physical activities and household chores – I'm too old to remember when and how many hours I did these things *(S: ≥ 50 W)*.
Some of it was hard – exercise, alcohol *(P: < 50 W)*.
It was difficult remembering that far back *(P: < 50 B)*.
Difficult to recall weight *(P: < 50 W)*.
Spent a lot of time trying to recall details that happen over 69 years ago *(S: ≥ 50 B)*.
Somewhat difficult trying to recall everything I did at a certain age. Don't think recalling the hours I spent on certain activity necessary *(P: < 50 B)*.

4. ***What did you think about the overall survey package including Items A – D (Confidential Locator Form, Life Events Calendar, Continuation Pages and Body Size Picture)?***

Very good *(P: < 50 W)*.
Good *(S: ≥ 50 B; S: ≥ 50 W)*.
Very explanatory and helpful *(P: ≥ 50 B)*.
Helpful *(P: < 50 B)*.
It was somewhat helpful *(P: < 50 B)*.
I think it was fine *(P: < 50 W)*.
Overall, it was fine *(P: ≥ 50 B)*.

The life events calendar is useful to answer the life history survey but it takes easily 90 minutes to complete the package and many could take longer *(S: ≥ 50 W)*.
It took longer than I thought it would *(S: ≥ 50 W)*.

The body size picture should show more of child size figures *(P: < 50 B)*.
Long; body picture didn't seem accurate *(P: < 50 B)*.

5. ***Any additional comments?***

Women should make copies for their daughters and grandchildren. May be useful in the future *(S: ≥ 50 W)*.
The booklet was very eye appealing. I like the color coding and the way it was put into a booklet *(S: ≥ 50 W)*.
I hope this survey will be helpful *(P: < 50 B)*.
Sorry I wasn't able to recall all the information requested *(S: ≥ 50 B)*.

Send a reminder call before the interview *(P: < 50 W)*.

Long *(P: < 50 B)*.
Just thought survey was long. Would not have completed it on my own *(P: < 50 B)*.

III. Modifications/Additions (Suggested changes are in *italics*.)

1. Add mail and return date to the survey.

2. Add "circle the number or letter that best matches your response" to the first two pages.

3. Add " → Go To __ " notes next to skip patterns.

4. Remove lines in front of [ ] in a question that refer to a specific category in the column of a table (i.e., AGE) and capitalize bracketed word.

5. Background Information (Page 2, questions 1 – 8): Add separate "Office Use Only" column for coding written data.

6. Medical History (Page 5, question 1): Add more space for subjects to record under Other Medical Problems, Specify category.

5. Pregnancy (Page 6, question 2G): Move breast feeding location question (equally, left or right) as second breast feeding question; and combine questions 2E and 2F to "How old was the child when you started giving him/her formula, milk or food?"

6. Menstrual and Menopausal History (Page 8, question 4A): Delete question because it is asked in question 2.

7. Menstrual and Menopausal History (Page 8, question 4B): Change to "On average, how many days was it from the **first day of one period** to the **first day of your next period** *(a complete menstrual cycle)*?"

8. Menstrual and Menopausal History (Page 10, question 5): Change to "What month and year did you have your **last** period, even if it was *some time* ago?"

9. Other Menstrual Conditions (Page 12, question 1): Add specific outcomes for these conditions: Surgery, Prescription Medication and Other Procedures

10. Contraceptive History (page 14, question 2): Change directions to indicate "[If you answered ***NO to questions 7, 8, 9 and 10*** above, skip the rest of this section and go to the Hormone Medication History section on page 16.]

11. Household Physical Activity (Page 26, question 1): Make example more specific and increase "Time per Day" from 30 minutes to 2 hours and 30 minutes.

12. Farm and Garden History (Page 29, question 1): Change to read "Have you ever *lived or worked* on a farm for more than 6 months?" (Are we after chronic exposure or intermittent summer exposure?)

13. Family History (Page 30, question 1): Change to "Do you know the general medical history of your biologic family?".

14. Family History (Pages 31 – 33, questions 3, 5 and 7): Add "(both full and half)" sisters notation for family history information.

15. Family History (Pages 30 – 35, question 2B): Add "Don't Know" option under relative still living question.

16. Family History (Pages 30 – 35, question 2D): Add more space for subjects to record under Other category.

IV. Questions/Problems to Resolve:

1. Pregnancy History (Page 6, question 2E): What if the mother went from breast feeding straight to regular milk instead of infant formula? Would they answer "Yes" to the child getting at least half of its food from infant formula while still being breast fed? (See Modification #5)

2. Menstrual and Menopausal History (Page 8, question 4): Do we need the phrase "Not during times when you pregnant or nursing, or using birth control pills, shots or implants, or fertility drugs" as part of the regular period question? (It was taken from the CARE survey; it seems confusing to respondents: See Modification #6)

3. Tobacco (Page 22, question 2): How should smoking less than 1 – 2 cigarettes per day (lowest category listed) be recorded, if at all?

4. Family History (Page 31, question 4): How should cancer diagnosed among half sisters be recorded?

5. Life Events Calendar (Item B): Do we need them to return the calendar or should they keep it for their own record?

APPENDIX B.

Risk Factor Questionnaire

WOMEN'S HEALTH STUDY

LIFE HISTORY SURVEY

Henry Ford Health System
Department of Biostatistics and Research Epidemiology
One Ford Place, Suite 3E
Detroit, MI 48202-3450

WOMEN'S HEALTH STUDY

FOR OFFICE USE ONLY:	
Study ID:	_ _ _ _ _ _ _ _ _
Survey mail date:	_ _ / _ _ / _ _ _ _
Survey comp. date:	_ _ / _ _ / _ _ _ _
Interviewer ID:	_ _ _
Outcome Code:	_ _ _ _ _

LIFE HISTORY SURVEY

Table of Contents

INSTRUCTIONS 1

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Instructions

The ***Women's Health Study*** **Life History Survey** will ask you about your medical, lifestyle, work and family history. The survey package contains the following items:

- ✓ Life History Survey
- ✓ Life Events Calendar (Item A)
- ✓ Continuation Pages for Pregnancy and Family History (Item B)
- ✓ Body Size Picture (Item C)
- ✓ Postage-paid return envelope

1. To help you recall the survey responses easier, start by recording important events and dates in your life on the **Life Events Calendar (Item A) before completing the survey.**

2. Once you have filled in the **Life Events Calendar**, begin working on the survey. Record one answer for each question, unless the instructions say differently. For questions listed on the left column, please write or circle the number that goes with your answer in the right-hand column. For questions listed in a table, please check, circle or write your answers in the table. Answer each question to the best of your knowledge. There is no right or wrong answer.

   Please use the **Continuation Pages for Pregnancy and Family History (Item B)** to record additional pregnancy or family history information that could not be listed on the survey. The **Body Size Picture (Item C)** will be used to help you fill in the Body section on pages 18 – 19.

   Because it is important to answer the questions as best as you can remember, you may want to sit down and work on the survey over a few days instead of all at once. It should take you about one hour to complete the survey. If you have any questions about filling out any of the forms, feel free to call Angela Blount at (313) 874-6232.

4. When you have finished the survey and the other forms, please check each page to make sure you have answered all questions that apply to you. Place the ***Women's Health Study*** **Life History Survey,** and **Continuation Pages for Pregnancy and Family History** in the postage-paid return envelope and mail to Henry Ford Health System, Biostatistics and Research Epidemiology, One Ford Place, Suite 3E, Detroit, MI, 48202-3450. If you decide not to complete the survey, please use the envelope to return the materials to us.

All information you provide will be kept confidential and will not affect your medical care. Only the researchers involved in this project will see your answers. Thank you for participating in this important research project to better understand and improve women's health.

Background Information

This section ask some general questions regarding your background. Please record your answer in the spaces provided.

		OFFICE USE ONLY
1. In what state/province and country were you born?	_____ State/Province	[__ __]
	_____ Country	[__ __]
2. **Up to the age of 30**, how many years did you live in each of the following four types of residential area, and the state (if in the United States) or country:		
Type of Residential Area	# Years State/Country	
1. A large city in a metropolitan area (e.g., Detroit, Chicago)	____ _____	[__ __]
2. A suburban city that is part of a metropolitan area (e.g., Southfield, Troy, Livonia)	____ _____	[__ __]
3. A small to medium town distant from a metropolitan area (e.g., Port Huron, Battle Creek)	____ _____	[__ __]
4. A rural area or on a farm	____ _____	[__ __]

The following questions are about your heritage, social setting and culture. This is useful information since some diseases are more common in some ethnic or cultural groups than others. Please write or circle the number that best matches your response to each question.

3. In which of the following categories would you classify yourself?	1. White/Caucasian 2. Black/African American 3. Hispanic/Latino 4. Asian/Pacific Islander 5. Middle Eastern 6. Native American/American Indian 7. Alaskan Native/Aleut/Eskimo 8. Other group(s), *Please Specify:* _____	**OFFICE USE ONLY** [__]
4. Is there an ethnic group or ancestry with which your family household identifies such as Korean, Mexican, Chaldean, Puerto Rican, etc.?	0. No 1. Yes, *Please Specify:* _____	[__]
5. What country are most of your father's ancestors from?	_____	[__]
6. What country are most of your mother's ancestors from?	_____	[__]
7. What religion were you raised in as a child?	1. None Christian Denominations: 2. Baptist 3. Catholic 4. Congregationalist 5. Eastern Orthodox 6. Episcopal 7. Jehovah's Witness 8. Lutheran 9. Methodist/AME/CME 10. Mormon/Latter Day Saints 11. Presbyterian 12. Quaker 13. Seventh Day Adventists 14. Unitarian 15. Protestant, Not Specified 16. Christian, Not Specified 17. Jewish 18. Muslim 19. Other, *Please Specify:* _____	[__]

OFFICE USE ONLY

8. What religion have you practiced most of your adult life?

1. None

Christian Denominations:

2. Baptist
3. Catholic
4. Congregationalist
5. Eastern Orthodox
6. Episcopal
7. Jehovah's Witness
8. Lutheran
9. Methodist/AME/CME
10. Mormon/Latter Day Saints
11. Presbyterian
12. Quaker
13. Seventh Day Adventists
14. Unitarian
15. Protestant, Not Specified
16. Christian, Not Specified
17. Jewish
18. Muslim
19. Other, *Please Specify:*

_____ [__ __]

9. What is the highest grade or level of schooling you have completed?

1. Grade school (less than 8 years)
2. Some high school (8 - 11 years)
3. Completed high school or GED
4. Vocational school
5. Some college
6. Completed college
7. Post-graduate school

10. What is your current marital status?

1. Married or Living as married
2. Widowed
3. Divorced
4. Separated
5. Never Married

11. What is your date of birth?

__ __ / __ __ / __ __ __ __
mm dd yyyy

Medical History

1. Has a doctor ever told you had any of the following conditions? Please place a check **in the box** next to each condition you have ever been diagnosed with.

☐ Chicken Pox	☐ Arthritis (Acute)	☐ Kidney Disease
☐ Measles	☐ Arthritis (Chronic)	☐ Immune System Disorder
☐ Mumps	☐ Hyperthyroid Disease	☐ Stroke
☐ Poliomyelitis (Polio)	☐ Hypothyroid Disease	☐ Transient Ischemic Attack (TIA)
☐ Typhoid	☐ Parathyroid Disease	☐ Food Allergies
☐ Shingles Zoster	☐ Pituitary Disease	☐ Drug Allergies
☐ Herpes Simplex	☐ Hypoglycemia	☐ Hay Fever
☐ Pneumonia	☐ Vitamin B1 Deficiency	☐ Other Allergies
☐ Mononucleosis (Mono)	☐ Vitamin B12 Deficiency	☐ Epilepsy/Seizures/Convulsions
☐ Meningitis	☐ Folate Deficiency	☐ Psychiatric Conditions
☐ Encephalitis	☐ Asthma	Specify: _____ [__ __]
☐ Multiple Sclerosis (MS)	☐ Other Respiratory Disease	☐ Any Type of Cancer
☐ Toxoplasmosis	☐ Migraine Headaches	Specify: _____ [__ __]
☐ Tuberculosis (TB)	☐ Clinical Depression	Specify: _____ [__ __]
☐ Heart Disease	☐ Hypertension (High Blood Pressure)	☐ Other Medical Conditions
☐ Diabetes ('Sugar')	☐ Anemia or Other Blood Disorder	Specify: _____ [__ __]
☐ Stomach or Other Digestive Disorder	☐ Liver Disease	Specify: _____ [__ __]

2. Have you ever had medical radiation (x-rays) to diagnose or treat any of the following conditions:

1. Tuberculosis	0. No	1. Yes	9. Don't Know
2. Postpartum mastitis (inflammation of the breast)	0. No	1. Yes	9. Don't Know
3. Other benign (non-cancerous) breast condition	0. No	1. Yes	9. Don't Know
4. Ankylosing spondylitis (type of rheumatoid arthritis)	0. No	1. Yes	9. Don't Know
5. Scoliosis (curved spine)	0. No	1. Yes	9. Don't Know
6. Tinea capitis (ringworm of the scalp)	0. No	1. Yes	9. Don't Know
7. Enlarged thymus	0. No	1. Yes	9. Don't Know
8. Skin hemangioma (benign tumor on the skin)	0. No	1. Yes	9. Don't Know
9. Childhood cancer (e.g., leukemia)	0. No	1. Yes	9. Don't Know
10. Hodgkin's disease	0. No	1. Yes	9. Don't Know

Pregnancy History

This section asks about all pregnancies you have had. This includes live births, stillbirths, miscarriages, abortions, and tubal (in the tubes) and other ectopic (outside the womb) pregnancies. The medical changes your body goes through during pregnancy may effect your health later on.

1. Have you ever been pregnant?

   0. No → **GO TO Page 8**
   1. Yes

   [If NO, skip the rest of this section and go to the <u>Menstrual and Menopausal History</u> section on page 8.]

2. For each pregnancy you have ever had, we would like to ask your age at the time of the pregnancy, outcome and length of the pregnancy in either weeks or months, and your breast feeding patterns. You can use the **Life Events Calendar (Item A)** to help you with this section. [If you have had more than 6 pregnancies, please record those pregnancies on the **Continuation Pages for Pregnancy History (Item B)**.]

	1st Pregnancy	2nd Pregnancy	3rd Pregnancy
How old were you at the start of your [1st/2nd] pregnancy?	_____ age in years	_____ age in years	_____ age in years
In weeks or months, what was the length of that pregnancy?	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months
What was the outcome of that pregnancy? [If **Answer 4 – 8**, skip to next pregnancy.]	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy
Did you breast feed? [*IF **No or Not Applicable**, skip to next pregnancy.]	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*
Did you breast feed using both breasts equally, or more use of the left or right breast?	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know
How old was the child when you started giving him/her formula, milk or food?	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months
How old was the child when you stopped breast feeding completely?	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months	_____ weeks **OR** _____ months

Pregnancy History (cont.)

	4th Pregnancy	5th Pregnancy	6th Pregnancy
How old were you at the start of your [4th/5th] pregnancy?	____ age in years	____ age in years	____ age in years
In weeks or months, what was the length of this pregnancy?	____ weeks **OR** ____ months	____ weeks **OR** ____ months	____ weeks **OR** ____ months
What was the outcome of that pregnancy? [If **Answer 4 – 8**, skip to next pregnancy.]	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy
Did you breast feed? [*IF **No or Not Applicable**, skip to next pregnancy.]	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*
Did you breast feed using both breasts equally, or more use of the left or right breast?	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know
How old was the child when you started giving him/her formula, milk or food?	____ weeks **OR** ____ months	____ weeks **OR** ____ months	____ weeks **OR** ____ months
How old was the child when you stopped breast feeding completely?	____ weeks **OR** ____ months	____ weeks **OR** ____ months	____ weeks **OR** ____ months

Menstruation and Menopause History

Menstruation (when you start having menstrual periods) and menopause (when you stop having periods or the change of life) are very important times in a woman's life. When these life events occur may cause other body changes. You can use your **Life Events Calendar** to help you complete this section.

1. At what age or year did you have your first menstrual period?

   _____ age **OR** ____ year

2. Have your periods ever been regular, that is – you usually knew within one week when your next period would begin, during times when you were **NOT** pregnant or nursing, or using birth control pills, shots (such as Depo-Provera), implants (Norplant) or fertility drugs?

   0. No → **GO TO Question 4**
   1. Yes

   [If NO, skip to question 4.]

3. At what age did your periods become regular?

   _____ age **OR** ____ year

4. Now we would like to find out about the pattern of your menstrual periods during certain times of your life.

AGE	On average, how many days was it from the **first day of one period** to the **first day of your next period** (a complete menstrual cycle) when you were [AGE]?	On average, **how heavy were most days** of your menstrual flow when you were [AGE]?
10 – 19 years old	1. Less than 21 days 2. 21 – 25 days 3. 26 – 31 days 4. 32 – 39 days 5. 40 – 50 days 6. More than 50 days 7. Too Irregular 8. Not Applicable/No Periods 9. Don't Know	1. Light 2. Medium 3. Heavy 4. Very Heavy 9. Don't Know
20 – 29 years old	1. Less than 21 days 2. 21 – 25 days 3. 26 – 31 days 4. 32 – 39 days 5. 40 – 50 days 6. More than 50 days 7. Too Irregular 8. Not Applicable/No Periods 9. Don't Know	1. Light 2. Medium 3. Heavy 4. Very Heavy 9. Don't Know

Menstruation and Menopause History (cont.)

AGE	On average, how many days was it from the **first day of one period** to the **first day of your next period** (a complete menstrual cycle) when you were [AGE]?	On average, **how heavy were most days** of your menstrual flow when you were [AGE]?
30 – 39 years old	1. Less than 21 days 2. 21 – 25 days 3. 26 – 31 days 4. 32 – 39 days 5. 40 – 50 days 6. More than 50 days 7. Too Irregular 8. Not Applicable/No Periods 9. Don't Know	1. Light 2. Medium 3. Heavy 4. Very Heavy 9. Don't Know
40 – 49 years old	1. Less than 21 days 2. 21 – 25 days 3. 26 – 31 days 4. 32 – 39 days 5. 40 – 50 days 6. More than 50 days 7. Too Irregular 8. Not Applicable/No Periods 9. Don't Know	1. Light 2. Medium 3. Heavy 4. Very Heavy 9. Don't Know
50 – 59 years old	1. Less than 21 days 2. 21 – 25 days 3. 26 – 31 days 4. 32 – 39 days 5. 40 – 50 days 6. More than 50 days 7. Too Irregular 8. Not Applicable/No Periods 9. Don't Know	1. Light 2. Medium 3. Heavy 4. Very Heavy 9. Don't Know

5. What month and year did you have your **last** period, even if it was some time ago?

__ __ / __ __ __ __
month year

6. What is your current menstrual status?

[If you chose response 1 or 8, skip the rest of this section and go to the Other Menstrual Conditions section on page 12.]

Still having periods:

1. Having regular periods → **GO TO Page 12**
2. Having irregular periods
3. Having periods but possibly beginning menopause (change of life)
4. Still having periods and on hormone medication (hormone/estrogen replacement therapy)

Periods have stopped:

5. By themselves (natural menopause)
6. By surgical removal of uterus (womb) or both ovaries (surgical menopause)
7. By radiation or chemotherapy
8. By hormonal birth control use → **GO TO Page 12**
9. By other medical condition, *Please Specify:*

_____ [__ __]

7. Did you ever or are you currently using hormones either after female surgery or to treat or prevent symptoms of menopause (change of life)?

[If NO or DON'T KNOW, skip to question 9.]

0. No → **GO TO Q. 9**
1. Yes, after female surgery
2. Yes, for menopausal symptoms
9. Don't Know → **GO TO Q. 9**

8. Using these hormones may cause a woman to keep having periods. What was the date of your last menstrual period **before** you started using hormones?

__ __ / __ __ __ __
month year

9. Hot flashes, night sweats, and other symptoms sometimes occur around the time of menopause. Around this time and up to 5 years before menopause, did you have hot flashes, night sweats, or any other symptoms of menopause?

[If NO, NOT APPLICABLE or DON'T KNOW, skip to question 11.]

0. No → **GO TO Q. 11**
1. Yes
8. Not Applicable/Have not reached menopause → **GO TO Q. 11**
9. Don't Know → **GO TO Q. 11**

10. How old were you when you began having these symptoms?

_____ **OR** _ _ _ _
age year

11. Did your doctor or other health care provider ever tell you that you had completed menopause or the change of life?

[If NO or DON'T KNOW, skip question 12 and go to the <u>Other Menstrual Conditions</u> section on page 12.]

0. No → **GO TO Page 12**
1. Yes
9. Don't Know → **GO TO Page 12**

12. How old were you when your doctor or other health provider told you that you had completed menopause?

_____ **OR** _ _ _ _
age year

Menstrual Conditions

1. Now we would like to ask about certain menstrual diseases, conditions, and surgeries that you may have had.

CONDITION	Did a doctor or other health care provider ever tell you that you had any of the following conditions? **[*If NO, go to the next condition.]**	At what age did a doctor first tell you that you had this condition?	Have you ever been hospitalized, had surgery or other procedures, or been prescribed medication for this condition?
1st	Cysts on the ovary? 0. No* 1. Yes	_____ age in years	0. No 1. Yes, Surgery 2. Yes, Prescription medication 3. Yes, Other procedure *Specify*: _____ [__ __] 9. Don't Know
2nd	Endometriosis? 0. No* 1. Yes	_____ age in years	0. No 1. Yes, Surgery 2. Yes, Prescription medication 3. Yes, Other procedure *Specify*: _____ [__ __] 9. Don't Know
3rd	Fibroids, fibroid tumors, or uterine fibroids? 0. No* 1. Yes	_____ age in years	0. No 1. Yes, Surgery 2. Yes, Prescription medication 3. Yes, Other procedure *Specify*: _____ [__ __] 9. Don't Know
4th	Pelvic Inflammatory Disease (PID)? 0. No* 1. Yes	_____ age in years	0. No 1. Yes, Surgery 2. Yes, Prescription medication 3. Yes, Other procedure *Specify*: _____ [__ __] 9. Don't Know

2. Have you ever had a hysterectomy, that is – did you have your womb (uterus) removed, causing your menstrual periods to stop?

   [If NO or DON'T KNOW, skip to question 4.]

   0. No → **GO TO Q. 4**
   1. Yes
   9. Don't Know → **GO TO Q. 4**

3. What month and year did you have the hysterectomy?

   __ __ / __ __ __ __
   month year

4. Have you ever had any surgery where a part of one ovary, a whole ovary, or both of your ovaries were removed? (Please include any surgeries on your ovaries at the time of a hysterectomy and any cysts removed from the ovaries.)

   [IF NO or DON'T KNOW, skip the rest of this section and go to the <u>Contraceptive History</u> section on page 14.]

   0. No → **GO TO Page 14**
   1. Yes
   9. Don't Know → **GO TO Page 14**

5. How many ovarian surgeries have you have?

   _____
   # of surgeries

6. Now we would like some additional information about these surgeries.

SURGERY	What exactly was **<u>removed</u>** during the [1st/2nd] surgery on your ovaries?	What month and year did you have the [1st/2nd] surgery on your ovaries?
1st	1. One Ovary (total) 2. One Ovary (partial) 3. Both Ovaries (total) 4. Both Ovaries (partial) 5. Both Ovaries (one total, one partial) 9. Don't Know	__ __ / __ __ __ __ month year
2nd	1. One Ovary (total) 2. One Ovary (partial) 3. Both Ovaries (total) 4. Both Ovaries (partial) 5. Both Ovaries (one total, one partial) 9. Don't Know	__ __ / __ __ __ __ month year
3rd	1. One Ovary (total) 2. One Ovary (partial) 3. Both Ovaries (total) 4. Both Ovaries (partial) 5. Both Ovaries (one total, one partial) 9. Don't Know	__ __ / __ __ __ __ month year

Contraceptive History

The next questions are about methods of family planning or birth control that you or your partner may have used.

1. Have you or any partner ever used any methods of birth control?

   [IF NO, skip the rest of this section and go to the Hormone Medication History section on page 16.]

   0. No → **GO TO Page 16**
   1. Yes

2. Have you and any partner ever used any of the following birth control methods:

1. Condoms or rubbers	0. No	1. Yes	9. Don't Know
2. Diaphragm, cap, or sponge	0. No	1. Yes	9. Don't Know
3. Foam, jelly, cream, or suppositories	0. No	1. Yes	9. Don't Know
4. Rhythm, calendar, ovulation, or withdrawal	0. No	1. Yes	9. Don't Know
5. Tubes tied, tubal sterilization, female sterilization	0. No	1. Yes	9. Don't Know
6. Vasectomy or male sterilization or surgery	0. No	1. Yes	9. Don't Know
7. Birth control pills (BCs)	0. No	1. Yes	9. Don't Know
8. Birth control shots or injections (i.e., Depo-Prevera)	0. No	1. Yes	9. Don't Know
9. Subdermal (under the skin) implants (i.e., Norplant)	0. No	1. Yes	9. Don't Know
10. IUD or intrauterine device such as a loop or coil	0. No	1. Yes	9. Don't Know
11. Any other method	0. No	1. Yes, *Please Specify:*	

_____ [__ __]

[If NO to questions 7, 8, 9, AND 10 above, skip the rest of this section and go to the Hormone Medication History section on page 16.]

3. We are particularly interested in any birth control methods that you may have used that contained hormones. Certain hormones in contraceptives can affect the level of hormones that your body makes.

   For all hormonal contraceptives you have **EVER** used, we would like to ask you what type it was (birth control pill, shot, injection or implant) and when you started and stopped using that particular type of contraceptive. Remember to look at your **Life Events Calendar** to help you answer these questions.

TYPE	What was the [1st/2nd] type of contraceptive (birth control) you took?	What month and year did you **START** taking this contraceptive?	What month and year did you **STOP** taking this contraceptive? **[Write present date if currently taking medication.]**
1st	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
2nd	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
3rd	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
4th	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
5th	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
6th	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
7th	1. Birth control pills 2. Birth control shots or injections 3. Subdermal implants 9. Don't Know	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year

Hormone Medication History

We would like to ask you questions about any hormone medications that you might have used before or around menopause and then any other hormone medications such as those be used to treat certain conditions of the breasts, ovaries, or uterus. Please do not include any birth control pills, IUDs, shots, or implants that you have already mentioned. Please use your **Life Events Calendar** to help you answer this section.

1. Have you ever used any hormone medications just before the start of menopause, around the time of menopause, or after menopause?

   [IF NO or NOT APPLICABLE, skip to question 3.]

   0. No → **GO TO Q. 3**
   1. Yes
   8. Not Applicable/Have not reached menopause → **GO TO Q. 3**

2. For each type of hormone medication you took **around the time of menopause**, we would like to ask the name of the hormone medication you took, reasons for taking that hormone [you may choose more than one] and the dates you started and stopped taking it.

TYPE	What was the name of the [1st/2nd] type of hormone medication you took? [Write **"DK"** if you Don't Know the name.]	Which of the following were reasons you took this medication? **[Please circle all that apply for each medication.]**	What month and year did you **START** taking this hormone medication?	What month and year did you **STOP** taking this hormone medication? **[Write present date if currently taking medication.]**
1st	_____ [__ __]	1. Irregular menstrual bleeding 2. Heavy menstrual bleeding 3. Delay of menopause/change of life 4. Hot flashes 5. Sweating 6. Vaginal dryness 7. Bladder problems 8. Depression or anxiety 9. After uterus or ovary removal 10. Prevention/treatment of bone loss 11. Prevention/treatment of heart disease 12. Other reason, *please specify*: _____ [___]	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
2nd	_____ [__ __]	1. Irregular menstrual bleeding 2. Heavy menstrual bleeding 3. Delay of menopause/change of life 4. Hot flashes 5. Sweating 6. Vaginal dryness 7. Bladder problems 8. Depression or anxiety 9. After uterus or ovary removal 10. Prevention/treatment of bone loss 11. Prevention/treatment of heart disease 12. Other reason, *please specify*: _____ [___]	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year

3. Have you ever used any other type of hormone medications that you have **NOT** already mentioned to treat, for example, severe menstrual cramps, acne, or ovarian or breast problems?

0. No → **GO TO Page 18**
1. Yes

[If NO, skip the rest of this section and go to the <u>Body</u> section on page 18.]

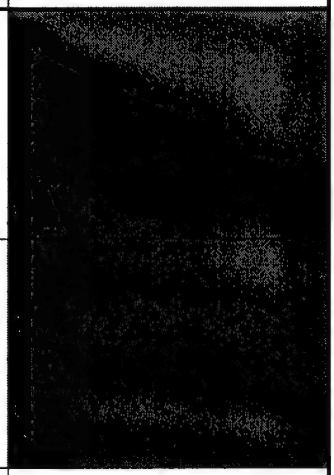
4. For hormone medications you have **NOT** already mentioned, we would like to ask the type of hormone medication you took, reasons for taking that hormone [you may choose more than one] and the dates you started and stopped taking it. Please do not include any birth control pills, shots, or implants that you have already mentioned.

TYPE	What was the name of the [1st/2nd] type of other hormone medication you took? [Write **"DK"** if you Don't Know the name.]	Which of the following were reasons you took this medication? **[Please circle all that apply for each medication.]**	What month and year did you **START** taking this hormone medication?	What month and year did you **STOP** taking this hormone medication? **[Write present date if currently taking medication.]**
1st	_____ [__ __]	1. Acne 2. Excessive hair growth or hirsutism 3. Endometriosis 4. To promote pregnancy/fertility 5. To prevent miscarriage 6. Problems with ovaries (i.e., cysts) 7. Polycystic ovarian disease 8. Breast tenderness or pain 9. Benign breast lumps or cysts 10. Premenstrual syndrome (PMS) 11. Severe menstrual cramps 12. Heavy menstrual bleeding 13. Other reason, *please specify*: _____ [___]	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year
2nd	_____ [__ __]	1. Acne 2. Excessive hair growth or hirsutism 3. Endometriosis 4. To promote pregnancy/fertility 5. To prevent miscarriage 6. Problems with ovaries (i.e., cysts) 7. Polycystic ovarian disease 8. Breast tenderness or pain 9. Benign breast lumps or cysts 10. Premenstrual syndrome (PMS) 11. Severe menstrual cramps 12. Heavy menstrual bleeding 13. Other reason, *please specify*: _____ [___]	__ __ / __ __ __ __ month year	__ __ / __ __ __ __ month year

Body Image

We would like to ask you some questions about your weight and body at different times in your life. How your body size changes through your life can be related to other body processes. You can use the **Life Events Calendar** to help you complete this section.

1. For each age period, we would like to know the weight group that would best describe your weight at that age, your average weight and using the **Body Size Picture (Item C)**, which body picture (# 1 – 9) best shows your body size at that time (during adult age periods only).

AGE	What was your weight group **AND** average weight in pounds when you were [AGE]? [Write "**DK**" if you Don't Know your weight at that time.]	Which Body Picture # (see Item C) best shows your body size when you were [AGE]?
8 –10 years old (Late Elementary School)	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	
11 – 13 years old (Middle/Junior High School)	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	
14 – 19 years old (High School/Late Teens)	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
20 – 24 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
25 – 29 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
30 – 34 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Very overweight 9. Don't Know	_____

Body Image (cont.)

AGE	What was your weight group **AND** average weight in pounds when you were [AGE]? [Write "**DK**" if you Don't Know your weight at that time.]	Which Body Picture # (see Item C) best shows your body size when you were [AGE]?
35 – 39 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
40 – 44 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
45 – 49 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
50 – 59 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
60 – 69 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
70 – 79 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____
80 – 89 years old	1. Underweight 2. Slightly underweight 3. Average weight 4. Slightly overweight **AND** _____ pounds 5. Overweight 9. Don't Know	_____

2. Were you teased in **elementary school** for being underweight?
   0. No
   1. Yes

3. Were you teased in **elementary school** for being overweight?
   0. No
   1. Yes

4. Were you teased in **middle school** for being underweight?
   0. No
   1. Yes

5. Were you teased in **middle school** for being overweight?
   0. No
   1. Yes

6. Were you teased in **high school** for being underweight?
   0. No
   1. Yes

7. Were you teased in **high school** for being overweight?
   0. No
   1. Yes

8. What has been your maximum height in feet and inches?
   _____ feet _____ inches

9. Are you left-handed, right-handed, or able to use both hands equally (ambidextrous)?
   1. Left handed
   2. Right handed
   3. Use both hands equally

Alcohol Consumption

Now we would like some information on your use of alcoholic beverages.

1. Have you ever drunk alcoholic beverages, such as beer, wine, or mixed drinks, at least once a month for 6 months or more?
   0. No → **GO TO Page 22**
   1. Yes

[If NO, skip the rest of this section and go to the Tobacco History section on page 22.]

2. Now we would like to find out about your average drinking habits during different decades of your life. [If you **did not drink** any beer, wine or mixed drinks in a decade, please write the amount as '**0**'.]

AGE	How many **Beers** did you usually drink in a day, week or month when you were [AGE]? **[Circle how often.]**	How many **Glasses of Wine** did you usually drink in a day, week or month when you were [AGE]? **[Circle how often.]**	How many **Mixed Drinks** did you usually drink in a day, week or month when you were [AGE]? **[Circle how often.]**	Did your tend to spread your drinks throughout the day/week/month or did you drink many drinks at one time?
10 – 19 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
20 – 29 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
30 – 39 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
40 – 49 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
50 – 59 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
60 – 69 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know
70 – 79 years old	_____ Beers **PER** 1. Day 2. Week 3. Month	_____ Wine **PER** 1. Day 2. Week 3. Month	_____ Drinks **PER** 1. Day 2. Week 3. Month	1. Spread out 2. Many at one time 9. Don't Know

Tobacco History

Now we would like some information on your use of tobacco products.

1. Have you ever smoked a total of 100 cigarettes or more in your life? 0. No → **GO TO Q. 3** 1. Yes

[If NO, skip to question 3 on page 23.]

2. We would like to find out your smoking patterns during different time periods in your life.

AGE	Did you smoke when you were [AGE]? [*If **NO**, skip to next age period.]	How many years did you smoke during this age period?	On average, how many cigarettes did you smoke **EACH DAY** (during the years you smoked)?	Did anyone living with you at that time smoke? [*If **NO**, skip to next age period.]	How many years during this period did they smoke?
8 – 10 years old (Late Elementary School)	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
11 – 13 years old (Middle/Junior High School)	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
14 – 19 years old (High School/ Late Teens)	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
20 – 29 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
30 – 39 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
40 – 49 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years

Tobacco History (cont.)

AGE	Did you smoke when you were [AGE]? [*If **NO**, skip to next age period.]	How many years did you smoke during this age period?	On average, how many cigarettes did you smoke **EACH DAY** (during the years you smoked)?	Did anyone living with you at that time smoke? [*If **NO**, skip to next age period.]	How many years during this period did they smoke?
50 – 59 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
60 – 69 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
70 – 79 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years
80 – 89 years old	0. No* 1. Yes	_____ years	1. Less than 3 cigarettes 2. 3 – 9 cigarettes 3. Half a pack (10) 4. One pack (20) 5. 1 ½ - 2 packs 6. More than 2 packs	0. No* 1. Yes	_____ years

3. Have you ever dipped snuff or chewed tobacco?

   [If NO, skip questions 4 and 5 and go to the <u>Physical Activity</u> section on page 24.]

   0. No → **GO TO Page 24**
   1. Yes

4. How many years did you dip snuff or chew tobacco?

   _____ years

5. How many times per day or week did you dip snuff or chew tobacco? [Answer in either Days **OR** Weeks.]

   _____ days **OR** _____ weeks

Physical Activity

We are interested in physical activities you have participated in during your lifetime. Specifically, we would like to ask you about your work, household and exercise activities starting with your earliest activities to the most recent. You can use the **Life Events Calendar** and the examples we have included in each table to help you complete these sections.

Work Physical Activity

1. Have you ever held a job outside the home for more than one month?

   0. No → **GO TO Page 26**
   1. Yes

   [If NO, skip the rest of this section go to the Household Physical Activity section on page 26.]

2. Now we would like to know about the level and amount of physical activity you have had at certain jobs. We will focus on jobs you have had for **at least 8 hours per week for 4 months of the year (128 hours per year or 2.5 hours per week per year)** over your lifetime, starting with your first job. Please do not include a job if you did not work on it for at least this amount of time.

   For each job, we would like to know your job title, what type of tasks you did on that job (i.e., typing, operating cash register, indoor painting), how old you were when you started and stopped that job, and the number of months per year, days per week, hours per day that you worked that job. Finally, we would like to know the physical intensity involved with the job. You can choose an intensity level for each job from the following:

Intensity Levels	Description
1. sedentary	mostly sitting with minimal walking
2. light	some standing and slow walking with little physical effort
3. moderate	continuous walking and carrying light loads with light sweating
4. heavy	using heavy equipment and carrying heavy loads with heavy sweating

JOB	What was the title of your [1st/2nd] job?	Can you briefly describe what type of tasks you did for this job?	**OFFICE USE ONLY**	What age did you **START** this job?	What age did you **STOP** this job?	Months per Year	Days per Week	Time per Day		Intensity Level (1,2,3,4)
								Hrs	Min	
Example	File Clerk	-filed papers -answered phone		18	22	12	5	8	0	2
1st										
2nd										

Work Physical Activity (cont.)

JOB	What was the title of your [3rd/4th] job?	Can you briefly describe what type of tasks you did for this job?	**OFFICE USE ONLY**	What age did you **START** this job?	What age did you **STOP** this job?	Months per Year	Days per Week	Time per Day		Intensity Level (1,2,3,4)
								Hrs	Min	
3rd										
4th										
5th										
6th										
7th										
8th										
9th										
10th										
11th										
12th										
13th										

Household Physical Activity

1. Now we are going to ask you about your pattern of household and gardening activities during your lifetime. We will focus on activities you did for **at least 7 hours per week for 4 months of the year (112 hours per year or 2.15 hours per week per year)** over your lifetime based on intensity level, starting with your first household and gardening activities. Please do not include activities you performed for less than this time.

   It may help to consider what a typical day or week was like for you. Then think about the type of activities that you did in a typical day or week and how physically involved they were. For each of the physical intensity levels listed (light, moderate and heavy), record the types of activities performed at that level, the start and stop ages you performed those activities, and the number of months per year, days per week and hours per day you performed those activities. If the intensity level, start/stop ages or amount of time for an activity changed, record as a new type of household activity. Examples at each intensity level are listed below:

Intensity Levels:	Examples:
2. light (little physical effort)	ironing, washing dishes, cooking, laundry, vacuuming
3. moderate (light sweating)	scrubbing/polishing floors, mowing the lawn
4. heavy (heavy sweating)	moving furniture, digging a garden, home improvements

INTENSITY LEVEL	What was the 1st/2nd type of light/moderate/ heavy household activity you did?	**OFFICE USE ONLY**	What age did you **START** this activity?	What age did you **STOP** this activity?	Months per Year	Days per Week	Time per Day		Intensity Level (2,3,4)
							Hrs	Min	
Example: LIGHT	Cooking, washing dishes, laundry		13	42 (current age)	12	4	2	30	2
1st LIGHT									2
2nd LIGHT									2
1st MODERATE									3
2nd MODERATE									3
1st HEAVY									4
2nd HEAVY									4

Exercise, Sports and Hobby Activity

1: As our last type of physical activity, we would like to know about exercise, sports and hobby activities that you did during your lifetime starting with your childhood to your most recent activities. We will focus on exercise, sports or hobby activities you have done **at least 10 times during your lifetime** and for **at least 2 hours per week for 4 months of the year (32 hours per year or 40 minutes per week per year)**. Please do not include an activity if you did not do it for at least this amount of time.

Besides sports and exercise, we are also interested in knowing whether you walked or biked to work or school which you can include information on as you did with the other sports activities. For each of the physical intensity levels listed (sedentary, light, moderate and heavy), record the types of activities performed at that level, the start and stop ages you performed those activities, and the number of months per year, days per week and hours per day you performed those activities. If the intensity level, start/stop ages or amount of time for an activity changed, record as a new activity. Please begin by reporting the activities that you did during your school years including your gym classes. Examples at each intensity level are listed below:

Intensity Levels:	Examples:
1. sedentary (little physical effort)	knitting, jewelry making, basket weaving
2. light (some physical effort)	slow walking, golfing, bowling
3. moderate (light sweating)	fast walking, jogging, swimming
4. heavy (heavy sweating)	aerobics, running, tennis, basketball

INTENSITY LEVEL	What was the [1st/2nd] type of sedentary/light exercise activity you did?	**OFFICE USE ONLY**	What age did you **START** this activity?	What age did you **STOP** this activity?	Months per Year	Days per Week	Time per Day		Intensity Level (2,3,4)
							Hrs	Min	
Example: MODERATE	Gym class in high school		14	17	9	5		45	3
1st SEDENTARY									1
2nd SEDENTARY									1
3rd SEDENTARY									1
4th SEDENTARY									1
5th SEDENTARY									1
1st LIGHT									2

Exercise, Sports and Hobby Activity (cont.)

INTENSITY LEVEL	What was the [1st/2nd] type of light/moderate/ heavy exercise activity you did?	**OFFICE USE ONLY**	What age did you **START** this activity?	What age did you **STOP** this activity?	Months per Year	Days per Week	Time per Day		Intensity Level (2,3,4)
							Hrs	Min	
2nd LIGHT									2
3rd LIGHT									2
4th LIGHT									2
5th LIGHT									2
1st MODERATE									3
2nd MODERATE									3
3rd MODERATE									3
4th MODERATE									3
5th MODERATE									3
1st HEAVY									4
2nd HEAVY									4
3rd HEAVY									4
4th HEAVY									4
5th HEAVY									4

Agricultural History

1. Have you ever lived or worked on a farm for more than 6 months?

   [If NO, skip the rest of this section and go to Family History section on page 30.]

   0. No → **GO TO Page 30**
   1. Yes

2. Did you ever live or work on a farm where insecticides (insect killing chemicals) were used on livestock, crops, farm buildings or lots?

   [If NO, skip to question 5.]

   0. No → **GO TO Q. 5**
   1. Yes

3. What was the total number of years insecticides were used on the farm?

   _____ years

4. How many times per year were they used during this period?

   _____ times per year

5. Did you ever live or work on a farm where herbicides (weed and plant killing chemicals) were used?

   [If NO, skip to question 8.]

   0. No → **GO TO Q. 8**
   1. Yes

6. What was the total number of years herbicides were used on the farm?

   _____ years

7. How many times per year were they used during this period?

   _____ times per year

8. Did you ever live or work on a farm where fungicides (fungus killing chemicals) were used?

   [If NO, skip the rest of this section and go to the Family History section on page 30.]

   0. No → **GO TO Page 30**
   1. Yes

9. What was the total number of years fungicides were used on the farm?

   _____ years

10. How many times per year were they used during this period?

    _____ times per year

3. How many **sisters** (both full and half) do/did **you** have? _____

[If NONE [0] or DON'T KNOW, skip to question 5.]

4. Now we would like to get some information about your **sisters'** history of cancer.

RELATIVE	Is your [1st/2nd] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of her death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	What age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Sister 1	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 2	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 3	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 4	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Melanoma 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

5. How many **sisters** (both full and half) does/did your **mother** have? _____

[If NONE [0] or DON'T KNOW, skip to question 7.]

6. Now we would like to get some information about your **mother's sisters'** history of cancer.

RELATIVE	Is your mother's [1st/2nd] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of her death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	What age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Mother's Sister 1	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 2	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 3	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 4	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

7. How many **sisters** (both full and half) does/did your **father** have? _____

[If NONE [0] or DON'T KNOW, skip to question 9.]

8. Now we would like to get some information about your **father's sisters'** history of cancer.

RELATIVE	Is your father's [1st/2nd] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of her death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	What age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Father's Sister 1	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 2	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 3	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 4	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

9. How many **daughters** do/did **you** have? _____

[If NONE [0] or DON'T KNOW, skip to question 11.]

10. Now we would like to get some information about your **daughters'** history of cancer.

RELATIVE	Is your [1st/2nd] daughter still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of her death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	What age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Daughter 1	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 2	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 3	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 4	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

Now we would like to get some information about any men in your family who may have had prostate cancer.

11. Were any of your male relatives, such as your grandfathers, father or brothers, ever diagnosed with prostate cancer?

0. No → **GO TO Page 36**
1. Yes
9. Don't Know → **GO TO Page 36**

[If NO or DON'T KNOW, skip the rest of this section and go to the Mother's Prenatal History section on page 36.]

12. We are interested in knowing which male relatives (father, brothers, grandfathers, father's brothers, etc.) were diagnosed with prostate cancer and the age, in years or decade (i.e., 60s or 70s), they were diagnosed.

RELATIVE	What is your relationship to the [1st/2nd] male family member diagnosed with prostate cancer?	**OFFICE USE ONLY**	What age (years or decade) was he diagnosed with prostate cancer? [Write **"DK"** if you Don't Know.]
1st			_____ years or decade
2nd			_____ years or decade
3rd			_____ years or decade
4th			_____ years or decade
5th			_____ years or decade
6th			_____ years or decade
7th			_____ years or decade
8th			_____ years or decade

Mother's Prenatal History

Now we would like to get some information about your mother when she was pregnant with you. It is possible that some prenatal events may affect the health of the baby later on.

1. How old was your mother when you were born?

   _____ age

2. How many live birth pregnancies did your mother have before you were born?

   _____ # of live births

3. How many stillbirth pregnancies did your mother have before you were born?

   _____ # of stillbirths

4. Before you were born, how many of your mother's pregnancies were twins or multiple births?

   _____ # of multiple birth pregnancies

5. Were you a twin or part of a multiple birth (triplets, quadruplets, etc.)?

   [If NO, go to question 8.]

   0. No → **GO TO Q. 8**
   1. Yes

6. Were you and your twin (or multiple birth siblings) identical?

   0. No
   1. Yes

7. Was your twin (or any of your multiple birth siblings) female?

   0. No
   1. Yes

8. When you were born, did you weigh less than 5½ pounds, between 5½ and 9 pounds, or more than 9 pounds?

   1. Less than 5 ½ pounds
   2. 5 ½ - 9 pounds
   3. More than 9 pounds
   9. Don't Know

9. Did your mother smoke cigarettes when she was pregnant with you?

   0. No
   1. Yes
   9. Don't Know

10. Did your mother take a medicine to prevent miscarriage, such as diesthylstilbesterol (DES), when she was pregnant with you?

    0. No
    1. Yes, DES
    2. Yes, Other medicine
    9. Don't Know

Household Information

1. Including income provided by you, your spouse/partner, and any other persons living in your household, what was your total household income before taxes last year?

   1. Less than $10,000
   2. $10,000 - $19,999
   3. $20,000 - $34,999
   4. $35,000 - $49,999
   5. $50,000 - $74,999
   6. $75,000 or more

2. How many people, including yourself, were supported by your total household income last year?

   1. 1
   2. 2
   3. 3
   4. 4
   5. 5
   6. 6
   7. More than 6

3. Do you rent or own your home?

   1. Rent apartment/house
   2. Own condominium/house

4. How much is your monthly payment?

   $_____ per month

5. What is your social security number?

   ___ -- ___ -- ____

Contact Information

It would be a great help to us if you could provide the names and addresses of two people who you **DO NOT** live with that would remain in contact with you if you should move. We would only contact these individuals if we were unable to reach you at your home address.

1. Name of Contact_____

   Street Address_____

   City_____ State _____ Zip Code _____

   Area Code and Phone Number (_ _ _) _ _ _ -- _ _ _ _

   Relationship to you_____ [_ _]

2. Name of Contact_____

   Street Address_____

   City_____ State _____ Zip Code_____

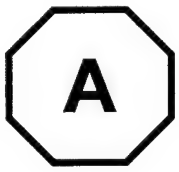
   Area Code and Phone Number (_ _ _) _ _ _ -- _ _ _ _

   Relationship to you_____ [_ _]

Thank you for completing the *Women's Health Study* Life History Survey. Please return the:

- ✓ **Life History Survey**
- ✓ **Continuation Pages for Pregnancy and Family History (Item B)**

in the self-addressed postage-paid envelope to Henry Ford Health System, Department of Biostatistics and Research Epidemiology, One Ford Place, Suite 3E, Detroit MI 48202-3450. If you have questions or need help completing the survey, please call (313) 864-6232.



WOMEN'S HEALTH STUDY

LIFE EVENTS CALENDAR

Thank you for participating in our study. To help tell us about yourself, we suggest that you fill in the attached table with important times in your life before completing the **Life History Survey**. As part of the survey, we will be asking you about various events in your life including your medical history, pregnancies, lifestyle, jobs, physical activity and your family history of cancer.

To fill in the table, you can list where you lived in the first (left hand) column, important life events in the second column (e.g. weddings, births, medical diagnoses), your education and jobs held in the third column, and any physical activities that you did in the final (right hand) column.

Please write in the attached table at what ages the following life events and activities happened in your life:

- Pregnancies*
- Menses (start of menstrual cycles) and menopause (end of menstrual cycles), if applicable*
- Diagnosis of medical conditions or surgeries performed*
- Weight changes*
- Alcohol and tobacco use throughout your life*
- Jobs held*
- Household, exercise and sports activities done throughout your life*
- Any diagnoses of cancer among your family members*

It may help you to remember the above events if you also record these items:

- Personal events such as weddings, births, deaths in family
- Places lived at different ages including moves to different places and homes

Please note that we will only be asking you about the items that have an asterisk (*) next to them.

This is a <u>shortened example</u> of what a completed life events calendar might look like:

Year	Age	Residence List city and state, and country, if outside the U.S.	Life Events List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	Education and Job History List when you did your education and all the jobs that you held.	Physical Activity History List leisure physical activities that you did at least 10 times during your lifetime.
1940-45	0-5	Detroit, MI	Born in 1940; sister born in 1945		
1946-50	6-10			Elementary School	Played baseball once a week
1952-55	12-15		Menstrual cycle began at age 13	Junior High School	Daily gym class
1955-58	15-18			High School; worked as a camp counselor during summers	Cheerleader, daily gym class
1958-62	18-22	Ann Arbor, MI	Grandmother diagnosed with breast cancer	College	Weekly swimming, rode bike to class
1963	23	Southfield, MI	Got married	Started working as teacher	Took up tennis (1 –2 times per week)
1970	30		First child was born		
1973	33		Second child was born		Started cross country skiing (4 – 6 times per month in the winter)
1984	44	Birmingham, MI	Father died	Promoted to principal	
1986	46				Stopped cross country skiing
1992	52		Started going through menopause		
1997	57		Uncle diagnosed with prostate cancer		Started walking daily

Please fill in all important events in your life. These reference points will be useful when answering the questions in the survey. You can fill in the calendar in whatever order is best for you.

Year	Age	**Residence** List city and state, and country, if outside the U.S.	**Life Events** List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	**Education and Job History** List when you did your education and all the jobs that you held.	**Physical Activity History** List leisure physical activities that you did at least 10 times during your lifetime.
	0-5				
	6-10				
	11-12				
	13				
	14				
	15				
	16				
	17				
	18				
	19				
	20				
	21				
	22				
	23				
	24				

Year	Age	**Residence** List city and state, and country, if outside the U.S.	**Life Events** List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	**Education and Job History** List when you did your education and all the jobs that you held.	**Physical Activity History** List leisure physical activities that you did at least 10 times during your lifetime.
	25				
	26				
	27				
	28				
	29				
	30				
	31				
	32				
	33				
	34				
	35				
	36				
	37				
	38				
	39				

Year	Age	**Residence** List city and state, and country, if outside the U.S.	**Life Events** List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	**Education and Job History** List when you did your education and all the jobs that you held.	**Physical Activity History** List leisure physical activities that you did at least 10 times during your lifetime.
	40				
	41				
	42				
	43				
	44				
	45				
	46				
	47				
	48				
	49				
	50				
	51				
	52				
	53				
	54				

Year	Age	**Residence** List city and state, and country, if outside the U.S.	**Life Events** List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	**Education and Job History** List when you did your education and all the jobs that you held.	**Physical Activity History** List leisure physical activities that you did at least 10 times during your lifetime.
	55				
	56				
	57				
	58				
	59				
	60				
	61				
	62				
	63				
	64				
	65				
	66				
	67				
	68				
	69				

Year	Age	**Residence** List city and state, and country, if outside the U.S.	**Life Events** List weddings, pregnancies, births, deaths, surgeries, cancer diagnoses, etc.	**Education and Job History** List when you did your education and all the jobs that you held.	**Physical Activity History** List leisure physical activities that you did at least 10 times during your lifetime.
	70				
	71				
	72				
	73				
	74				
	75				
	76				
	77				
	78				
	79				
	80				
	81				
	82				
	83				
	84				

B

FOR OFFICE USE ONLY:	
Study ID:	_ _ _ _ _ _ _ _ _
Survey mail date:	_ _ / _ _ / _ _ _ _
Survey comp. date:	_ _ / _ _ / _ _ _ _
Interviewer ID:	_ _ _
Outcome Code:	_____

WOMEN'S HEALTH STUDY

CONTINUATION PAGES

Pregnancy History

Family History

Continuation Pages: Pregnancy History

If you have had more than 6 pregnancies, use these pages to record information on those pregnancies. Remember to include live births, stillbirths, miscarriages, abortions, and tubal (in the tubes) and other ectopic (outside the womb) pregnancies. For each pregnancy, record your age at the time of the pregnancy, outcome of the pregnancy, length of time in either weeks or months, and your breast feeding patterns, if applicable.

	7th Pregnancy	8th Pregnancy	9th Pregnancy
How old were you at the Start of your [7th/8th] pregnancy?	______ age in years	______ age in years	______ age in years
In weeks or months, what was the length of this pregnancy?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months
What was the outcome of that pregnancy? [If **Answer 4 – 8**, skip to next pregnancy.]	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy
Did you breast feed? [*IF **No or Not Applicable**, skip to next pregnancy.]	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*
Did you breast feed using both breasts equally, or more use of the left or right breast?	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know
How old was the child when you started giving him/her formula, milk or food?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months
How old was the child when you stopped breast feeding completely?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months

	10th Pregnancy	11th Pregnancy	12th Pregnancy
How old were you at the start of your [10th/11th] pregnancy?	______ age in years	______ age in years	______ age in years
In weeks or months, what was the length of this pregnancy?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months
What was the outcome of that pregnancy? [If **Answer 4 – 8**, skip to next pregnancy.]	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy	1. Single Live Birth 2. Multiple Birth, Any Living 3. Multiple Birth, None Living 4. Stillbirth 5. Miscarriage, Doctor Confirmed 6. Miscarriage, Not Confirmed 7. Induced Abortion 8. Ectopic or Tubal Pregnancy
Did you breast feed? [*IF **No or Not Applicable**, skip to next pregnancy.]	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*	0. No* 1. Yes 8. Not Applicable*
Did you breast feed using both breasts equally, or more use of the left or right breast?	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know	1. Equal 2. Left 3. Right 9. Don't Know
How old was the child when you started giving him/her formula, milk or food?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months
How old was the child when you stopped breast feeding completely?	______ weeks **OR** ______ months	______ weeks **OR** ______ months	______ weeks **OR** ______ months

Continuation Pages: Family History

If you have more than 4 sisters or daughters, or your father or mother have more than 4 sisters, please record their history on these pages.

1. Your **sisters'** history of cancer.

RELATIVE	Is your [5th/6th] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of her death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	At what age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Sister 5	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 6	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 7	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Sister 8	0. No 1. Yes* 9. Don't Know	_____ Years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Melanoma 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

2. Your **mother's sisters'** history of cancer.

RELATIVE	Is your mother's [5th/6th] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	At what age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Mother's Sister 5	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 6	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 7	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Mother's Sister 8	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Melanoma 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

3. Your **father's sisters'** history of cancer.

RELATIVE	Is your father's [5th/6th] sister still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	At what age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Father's Sister 5	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 6	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 7	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Father's Sister 8	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Melanoma 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

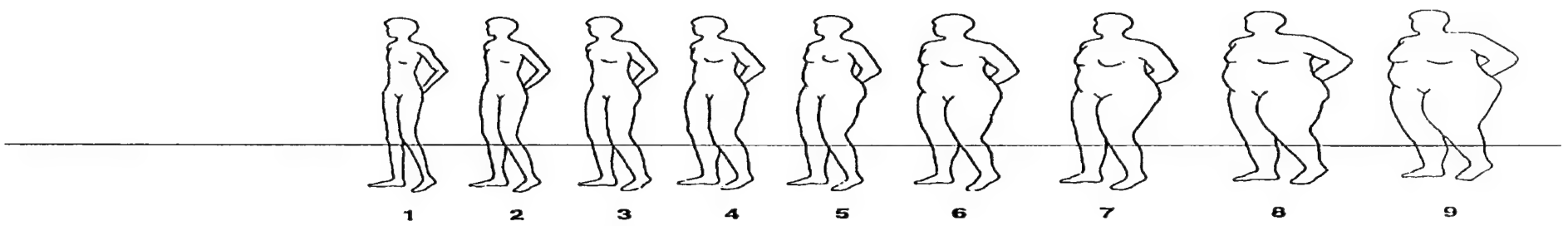
4. Your **daughters'** history of cancer.

RELATIVE	Is your [5th/6th] daughter still living? [*If **YES**, skip next question.]	How old (years or decade) was she at the time of death?	Did she ever have cancer? [*If **NO or DON'T KNOW**, skip to the next relative.]	What type(s) of cancer did she have? **[Circle all that apply.]**	At what age (years or decade) was this cancer diagnosed? [Write **"DK"** if you Don't Know.]
Daughter 5	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 6	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 7	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Skin (melanoma) 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade
Daughter 8	0. No 1. Yes* 9. Don't Know	_____ years or decade	0. No* 1. Yes 9. Don't Know*	1. Breast 2. Ovarian 3. Cervical 4. Uterine 5. Unknown female genital organ 6. Colorectal 7. Melanoma 8. Lung 9. Other, *Specify*: _____[___]	_____ _____ _____ _____ _____ _____ _____ _____ _____ years or decade

C

WOMEN'S HEALTH STUDY

BODY SIZE PICTURE



APPENDIX C.

Other Forms

BENIGN BREAST DISEASE PATHOLOGY REVIEW FORM

PLACE LABEL HERE:
MRN
Pathology # Specimen #
Date of Pathology Report

PRF Outcome: ❑1 BBD ❑2 CIS ❑3 Cancer ❑4 No Tissue

BIOPSY REVIEWER

❑0 No ❑1 Yes Usha Raju
❑0 No ❑1 Yes Varsha Shah
❑0 No ❑1 Yes Sandra Wolman
❑0 No ❑1 Yes Murali Verma

FORM COMPLETION DATE

__/__/____

TYPE OF BIOPSY

❑1 Needle
❑2 Excision
❑3 Simple Mastectomy
❑4 Modified Radical Mastectomy
❑7 Other_____
❑9 Unknown

LOCALIZATION

❑0 No
❑1 Yes
Diagnostic Concordance:
❑1 Definite ❑2 Probable ❑3 Uncertain _____
❑9 Unknown

LOCATION OF BREAST BIOPSY

❑1 Left
❑2 Right
❑3 Both
❑9 Unknown

LOCALIZATION MARKER

❑0 No ❑1 Yes Dye
❑0 No ❑1 Yes Wire

❑0 No ❑1 Yes Needle
❑0 No ❑1 Yes Other_____

BREAST QUADRANT

❑1 Upper Inner ❑4 Upper Outer
❑2 Lower Inner ❑5 Lower Outer
❑3 Central ❑9 Unknown

GROSS FINDINGS

❑1 No lesion
❑2 Cyst(s) ❑1 Solitary ❑2 Multiple
❑3 Mass(es) ❑1 Solitary ❑2 Multiple
Size of Largest Mass/Cyst ___ . ___ cm
❑7 Other_____
❑9 Unknown

MAMMARY EPITHELIAL TISSUE BIOPSY

❑0 No
❑1 Yes

MICROSCOPIC FINDINGS

SIMPLE APOCRINE METAPLASIA

PRESENT	FOCI	CALCIFICATIONS
❑0 No	❑1 1	❑0 No
❑1 Yes	❑2 2-5	❑1 Yes
	❑3 6+	

CYSTS

PRESENT	FOCI	CALCIFICATIONS
❑0 No	❑1 1	❑0 No

PERIDUCTAL MASTITIS/DUCT ECTASIA

PRESENT
- ❑0 No
- ❑1 Yes

CALCIFICATIONS
- ❑0 No
- ❑1 Yes

MASTITIS

PRESENT
- ❑0 No
- ❑1 Yes

FIBROSIS

PRESENT
- ❑0 No
- ❑1 Yes

CALCIFICATIONS
- ❑0 No
- ❑1 Yes

SQUAMOUS METAPLASIA

PRESENT
- ❑0 No
- ❑1 Yes

FOCI
- ❑1 1
- ❑2 2-5
- ❑3 6+

FIBROADENOMA

PRESENT
- ❑0 No
- ❑1 Yes

FOCI
- ❑1 1
- ❑2 2-5
- ❑3 6+

SIZE
___ . ___ cm

CALCIFICATIONS
- ❑0 No
- ❑1 Yes

BLOCK
_____

Associated Findings Within Lesion

HYPERPLASIA
- ❑0 No
- ❑1 Mild
- ❑2 Moderate/Florid

ADENOSIS
- ❑0 No
- ❑1 Yes

ADH
- ❑0 No
- ❑1 Yes

ALH
- ❑0 No
- ❑1 Yes

DCIS
- ❑0 No
- ❑1 Yes

LCIS
- ❑0 No
- ❑1 Yes

CYSTIC CHANGES
- ❑0 No
- ❑1 Yes

PLACE LABEL HERE

CELLULAR STROMA
- ❑0 No
- ❑1 Yes

SIMPLE ADENOSIS

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑1 ≤ 0.3 cm	❑0 No	_____
❑1 Mild	❑2 2-5	❑2 0.3 - 0.9 cm	❑1 Yes	
❑2 Moderate/Florid	❑3 6+	❑3 1.0 - 1.9 cm		
		❑4 ≥ 2.0 cm		

Associated Findings Within Lesion

ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No
❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes

SCLEROSING ADENOSIS

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑1 ≤ 0.3 cm	❑0 No	_____
❑1 Mild	❑2 2-5	❑2 0.3 - 0.9 cm	❑1 Yes	
❑2 Moderate/Florid	❑3 6+	❑3 1.0 - 1.9 cm		
		❑4 ≥ 2.0 cm		

Associated Findings Within Lesion

ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No
❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes

APOCRINE ADENOSIS

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑1 ≤ 0.3 cm	❑0 No	_____
❑1 Mild	❑2 2-5	❑2 0.3 - 0.9 cm	❑1 Yes	
❑2 Moderate/Florid	❑3 6+	❑3 1.0 - 1.9 cm		
		❑4 ≥ 2.0 cm		

Associated Findings Within Lesion

ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No
❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes

PLACE LABEL HERE

HYPERPLASIA WITHOUT ATYPIA (USUAL TYPE)

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑1 ≤ 0.3 cm	❑0 Nc	_____
❑1 Mild	❑2 2-5	❑2 0.3 - 0.9 cm	❑1 Yes	
❑2 Moderate/Florid	❑3 6+	❑3 1.0 - 1.9 cm		
		❑4 ≥ 2.0 cm		

HYPERPLASIA WITHOUT ATYPIA (APOCRINE TYPE)

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑1 ≤ 0.3 cm	❑0 No	_____
❑1 Mild	❑2 2-5	❑2 0.3 - 0.9 cm	❑1 Yes	
❑2 Moderate/Florid	❑3 6+	❑3 1.0 - 1.9 cm		
		❑4 ≥ 2.0 cm		

ADH*

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

ALH*

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

PAPILLOMA

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

Associated Findings Within Lesion

HYPERPLASIA	ADENOSIS	ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No	❑0 No	❑0 No
❑1 Mild	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes
❑2 Moderate/Florid					

PLACE LABEL HERE

RADIAL SCAR

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

Associated Findings Within Lesion

HYPERPLASIA	ADENOSIS	ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No	❑0 No	❑0 No
❑1 Mild	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes
❑2 Moderate/Florid					

LCIS*

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

DCIS*

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5		❑1 Yes	
	❑3 6+			

INVASIVE CARCINOMA

PRESENT	FOCI	SIZE	BLOCK
❑0 No	❑1 1	___ . ___ cm	_____
❑1 Yes	❑2 2-5		
	❑3 6+		

PLACE LABEL HERE

LYMPHOCYTIC INFILTRATE

PRESENT	FOCI	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	❑0 No	_____
❑1 Yes	❑2 2-5	❑1 Yes	
	❑3 6+		

Associated Findings With Lesion

NORMAL LOBULES	DUCT ECTASIA	DCIS	CYST(S)	OTHER _____
❑0 No	❑0 No	❑0 No	❑0 No	❑0 No
❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes

PHYLLODES TUMOR

PRESENT	CELLULAR STROMA	STROMAL OVERGROWTH	SIZE	MITOSIS
❑0 No	❑0 No	❑0 No	___ ___ . ___ cm	_____ Count / 10 HPF
❑1 Yes	❑1 Yes	❑1 Yes		

HYPERPLASIA	MARGINS	TUMOR TYPE
❑0 No	❑0 Negative	❑1 Benign
❑1 Mild	❑1 Positive	❑2 Indeterminate
❑2 Moderate/Florid	Distance: ___ . ___ cm	❑3 Malignant

OTHER (please specify) _____

PRESENT	FOCI	SIZE	CALCIFICATIONS	BLOCK
❑0 No	❑1 1	___ . ___ cm	❑0 No	_____
❑1 Yes	❑2 2-5	❑99 N/A	❑1 Yes	
	❑3 6+			

Associated Findings Within Lesion

HYPERPLASIA	ADENOSIS	ADH	ALH	DCIS	LCIS
❑0 No	❑0 No	❑0 No	❑0 No	❑0 No	❑0 No
❑1 Mild	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes	❑1 Yes
❑2 Moderate/Florid					

*ADH: Atypical Ductal Hyperplasia
ALH: Atypical Lobular Hyperplasia
LCIS: Lobular Carcinoma In Situ
DCIS: Ductal Carcinoma In Situ

PLACE LABEL HERE

BENIGN BREAST DISEASE STUDY

LOCATOR FORM

All study subjects have been mailed an introductory letter briefly explaining the study. As an interviewer, you will be calling subjects to administer a short health survey. All numbered survey questions should be read. Instructions and survey codes are enclosed in [ ].

INTRODUCTION:

"Hello may I speak with **[Subject]**? Hello, my name is **[Interviewer]** and I am calling from a women's health study being conducted by Henry Ford Health System. We recently sent a letter telling you about our study looking at the prevention of disease among women. As a woman who at some time has received medical care at Henry Ford, I would like to ask you some questions about your health. All information you provide will be strictly confidential. This will only take a few minutes."

[IF SUBJECT IS DECEASED OR UNABLE TO ANSWER THE QUESTIONS: Explain study to contact person and ask them if they will complete Locator Form questions #5 and 7 as it relates to the study subject. State that we may need to contact them for additional information about the subject. Ask the contact person for their name, address and phone number and record on the corrected side of the Data Sheet. Record who completed the form on page 6.]

[IF SUBJECT DID NOT RECEIVE THE LETTER: Paraphrase the letter to the subject. If they would like another copy of the letter sent to them, verify their name and address and inform them you will be calling back after the letter is mailed.]

1. On average, how often do you see your primary care physician? **[Read 1-4]** _____

    1. More than once a year
    2. Once a year
    3. Once every 2-3 years
    4. Less than every 4 years
    9. Don't Know

2. On average, how often do you receive a mammogram? **[Read 1-4]** _____

    1. More than once a year
    2. Once a year
    3. Once every 2-3 years
    4. Less than every 4 years
    9. Don't Know

3. On average, how often do you have a pap smear? **[Read 1-4]** _____

1. More than once a year
2. Once a year
3. Once every 2-3 years
4. Less than every 4 years
9. Don't Know

4. Have you ever been diagnosed with ovarian cysts? **[0=No, 1=Yes, 9=DK]** _____

5A. Have you ever had any type of breast procedure, such as a needle biopsy or a lump or cyst removed?

[0=No (Skip to 6A), 1=Yes, 9=DK] _____

5B. Can you tell me when you had your most recent breast procedure? _____ OR _____
Month/Year Age at Surgery

5C. At the time of this procedure, when you were not feeling well, say with a sore throat or other general illness, did you go to a primary care doctor at Henry Ford?

[0=No, 1=Yes, 9=DK] _____

6A. Have you ever had any <u>other</u> type of medical procedure where tissue, such as skin or a polyp, was removed?

[0=No (Skip to 7A), 1=Yes, 9=DK] _____

6B. Can you tell me what your most recent procedure was? _____

6C. And when did you have this procedure? _____ OR _____
Month/Year Age at Procedure

6D. Can you tell me the name and location of the medical facility or hospital where you had this procedure?

Name	City	State

7A. Have you ever been diagnosed with breast cancer?

[0=No (Skip to NO section below), 1=Yes, 9=DK] _____

7B. When were you diagnosed with breast cancer? _____ OR _____
Month/Year Age at Diagnosis

brcahfh [0=no, 1=Yes, 9=DK] ____

7C. Can you tell me the name and location of the medical facility or hospital where you were diagnosed?

Name	City	State

IF YES TO #7A:

"We are especially interested in learning more about breast cancer. We would like to contact you again to ask you some additional questions about your health. For that reason, I would like to take a minute to confirm location information with you. "

IF NO TO #7A:

"We are very interested in the prevention of disease among women. We may be contacting you again to ask you some additional questions about your health. For that reason, I would like to take a minute to confirm location information with you."

GO TO PRE-PRINTED DATA SHEET TO CONFIRM INFORMATION

8. If you have a vacation home or other residence, could you tell me the address, telephone number and time of year you are at that residence?

[0=No Other Residence (Skip to 9), 1=Yes] _____

Street Address _____

City, State, Zip Code and Country _____

Phone (___ ___ ___) ___ ___ ___ -___ ___ ___ ___

Time at Residence From (M/D): _____ / _____ To (M/D): _____ / _____

9. Can you tell me the names of two adults who live with you and what their relationship is to you?

[0=No/Lives Alone, 1=Yes, 2=Unwilling to State] _____

1. First and Last Name _____ Relationship_____

2. First and Last Name _____ Relationship_____

10. What is the name, address and telephone number of your current primary care physician or clinic?

[0=No Primary Care Physician, 1=Yes, 2=Unwilling to State] _____

Name of physician or clinic _____

Street Address _____

City, State, and Zip Code _____ _____

Phone (___ ___ ___) ___ ___ ___ -___ ___ ___ ___

11. It would be great help to us if you could provide us with the names and addresses of two people who you do not live with that could give us your new address should you move. We would only contact these people if we were unable to reach you at your home address.

[0=No One Available, 1=Yes, 2=Unwilling to State] _____

1. Name of Contact _____

   Street Address _____

   City, State, and Zip Code _____ _____

   Phone (___ ___ ___) ___ ___ ___-___ ___ ___ ___

   Relationship _____

2. Name of Contact _____

   Street Address _____

   City, State, and Zip Code _____ _____

   Phone (___ ___ ___) ___ ___ ___-___ ___ ___ ___

   Relationship _____

CLOSING:
"That all the information that I need today. Thank you for taking the time to respond to these questions. Your cooperation in this women's health study is greatly appreciated. "

Go to Page 6 to complete Interviewer Assessment

END OF INTERVIEW

INTERVIEW ASSESSMENT

Complete the following items after finalizing the interview.

1. Record subject's status. _____

    1. Alive, living in own or relative's home
    2. Alive, living in nursing home/residential care facility
    4. Deceased
    7. Other (specify) _____

2. Record who completed the Locator Form. _____

    1. Subject
    2. Spouse
    3. Offspring
    7. Other (specify relationship) _____

3. If Locator Form was not completed by subject, record why.

    [Skip if subject completed form or is deceased.] _____

    1. Physical illness or confinement
    2. Mental instability
    3. Difficulty understanding or speaking English
    4. Poor hearing or speech
    7. Other (specify) _____
    8. Not Applicable
    9. Don't Know

4. Record your perception of the subject's willingness to be contacted in the future. _____

    1. Willing
    2. Not willing
    7. Other (specify) _____
    9. Don't Know

5. Record any additional comments relevant to the interview:

_____

_____

_____

BENIGN BREAST DISEASE STUDY

MEDICAL RECORD ABSTRACT

MRN ___ ___ ___ ___ ___ ___ ___ ___ Follow-up Complete Yes No

Index Date ___ ___ / ___ ___ / ___ ___ Abstractor Status: 1. Complete/Finalized
2. Incomplete/Finalized
3. Chart Not Received

Date Abstracted ___ ___ / ___ ___ / ___ ___ ___ ___ Abstractor's Initials ___ ___ ___

DEMOGRAPHICS at time of chart abstraction:

1. Name: _____ [last] _____ [first] _____ [mi]

2. Social Security Number: ___ ___ ___ - ___ ___ - ___ ___ ___ ___

3. Date of Birth: ___ ___ / ___ ___ / ___ ___ ___ ___

4. Sex:
1=Female
2=Male

5. Race:
1=White/Caucasian
2=Black/Afrian American
3=Hispanic/Latino
4=Asian/Pacific Islander
5=Middle Eastern
6=Native American/American Indian
7=Other, specify_____
9=Unknown

6. Current Marital Status:
1=Divorced
2=Married
3=Single
4=Widowed
5=Legally separated
9=Unknown

7. Spouse's Name, if applicable: _____

8. Maiden Name: _____

9. Former Last Name: _____

10. Vital Status:
0=Deceased
1=Alive

11. Date of Vital Status Assessment: __ __ / __ __ / __ __ __ __

12. Insurance at Index Date:
1=HAP
2=Other HMO
3=Blue Cross/Blue Shield
4=Medicare
5=Medicaid
6=Other _____
7=None
9=Unknown
Date documented: __ __ / __ __ / __ __ __ __

13. Previous Insurance:
(w/in 10 yrs prior to index)
1=HAP
2=Other HMO
3=Blue Cross/Blue Shield
4=Medicare
5=Medicaid
6=Other _____
7=None
9=Unknown
Date documented: __ __ / __ __ / __ __ __ __

14. Highest Education:
1=Grade School (< 8 years)
2=Some High School (8 – 11 years)
3=Completed High School/GED
4=Vocational School
5=Some College
6=Completed College
7=Post-graduate School
9=Unknown

MEDICAL HISTORY

1. Hormonal Contraceptive Use **from beginning of chart up to index date**:

0=No
1=Yes
9=Unknown

Start date of use: __ __ / __ __ / __ __ __ __

Length of time (years): _____

Type:
1=Birth Control Pills
2=Shots or Injections
3=Subdermal Implants

Start date of use: __ __ / __ __ / __ __ __ __

Length of time (years): _____

Type:
1=Birth Control Pills
2=Shots or Injections
3=Subdermal Implants

2. Hormone Replacement Therapy Use **from beginning up to index date**:

0=No
1=Yes
9=Unknown

Date mentioned in chart: __ __ / __ __ / __ __ __ __

Start date: __ __ / __ __ / __ __ __ __

Stop date: __ __ / __ __ / __ __ __ __

Type:
1=Estrogen Alone
2=Estrogen plus Progesterone
3=Progesterone Alone

Date mentioned in chart: __ __ / __ __ / __ __ __ __

Start date: __ __ / __ __ / __ __ __ __

Stop date: __ __ / __ __ / __ __ __ __

Type:
1=Estrogen Alone
2=Estrogen plus Progesterone
3=Progesterone Alone

3. Other Medical Conditions diagnosed/mentioned **up to 10 years prior to index date**:

0=No
1=Yes
9=Unknown

Allergies:
____ Drug allergy
____ Food allergy
____ Hay fever
____ Other allergies

____ Anemia or other blood disorder
____ Arthritis (Non-inflammatory)
____ Arthritis (Rheumatoid)

Cardiovascular Diseases:
____ Heart disease
____ Hypertension (high blood pressure)

Cerebrovascular Diseases:
____ Stroke
____ Transient Ischemic Attack (TIA)

____ Diabetes ('sugar')
____ Folate deficiency
____ Hyperthyroid disease
____ Hypoglycemia
____ Hypothyroid disease
____ Immune system disorder

Infectious Diseases:
____ Chicken pox
____ Encephalitis
____ Herpes simplex
____ Measles
____ Meningitis
____ Mononucleosis (mono)
____ Mumps
____ Pneumonia

Infectious Diseases (cont.):
____ Poliomyelitis (polio)
____ Shingles zoster
____ Toxoplasmosis
____ Tuberculosis (TB)
____ Typhoid

____ Kidney disease
____ Liver disease

Neurologic/Psychiatric Disorders:
____ Clinical depression
____ Epilepsy/Seizures/Convulsions
____ Migraine headaches
____ Multiple Sclerosis (MS)
____ Psychiatric conditions requiring medication

____ Parathyroid disease
____ Pituitary disease

Respiratory Diseases:
____ Asthma
____ Emphysema
____ Other respiratory disease

____ Stomach or other digestive disorder
____ Vitamin B1 Deficiency
____ Vitamin B12 Deficiency

____ **Other Medical Conditions (specify):**

_____

_____

4. Mammography History **from beginning up to one year after index date**:

0=No
1=Yes
9=Unknown

Dates:	Results:	Result Codes:
___/___/_____	_____	1=Negative 2=Benign/Negative 3=Probably Benign 4=Suspicious 5=Highly Suspicious 8=Incomplete/Inconclusive 9=Unknown
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	

5. Breast Biopsy History from beginning **up to one year after index date**:

0=No
1=Yes
9=Unknown

Dates:	Results:	Result Codes:
___/___/_____	_____	1= Benign Breast Disease (BBD) 2= Ductal or Lobular Carcinoma In Situ (DCIS or LCIS) 3= Cancer (Carcinoma) 4= Both BBD and CIS/Cancer 5= Lumpectomy or Mastectomy (unilateral or bilateral) 6= Cosmetic Breast Reduction or Enlargement 7= Other Breast Biopsy (non-mammary epithelial biopsy of skin, nipple, fat, axillary lymph nodes, etc.) 8= Incomplete/Inconclusive 9=Unknown
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	
___/___/_____	_____	

BODY SIZE INFORMATION

1. Maximum Height (inches): _____ Date: ___ / ___ / _____

2. Weight closest to **index date** (pounds): _____ Date: ___ / ___ / _____

3. Weight during previous decade (pounds): _____ Date: ___ / ___ / _____

4. Weight during previous decade (pounds): _____ Date: ___ / ___ / _____

5. Weight during previous decade (pounds): _____ Date: ___ / ___ / _____

REPRODUCTIVE HISTORY from beginning of chart up to index date:

1. Age at Menarche (years): _____ [99=Unknown]

2. Age at First Birth (years): _____ [88=No Children; 99=Unknown]

3. Number of Pregnancies up to **index date**: _____ [99=Unknown]

4. Total Number of Pregnancies (gravida): _____ [99=Unknown]

5. Total Number of Births (para): _____ [99=Unknown]

6. Menopausal Status at **index date**:
   1=Pre-menopausal
   2=Peri-menopausal
   3=Post-menopausal
   9=Unknown

7. Year of Menopause: ____
   (skip if not post-menopausal)

8. Hysterectomy:
   0=No
   1=Yes
   9=Unknown

   Number of ovaries removed: _____

   Date of surgery: ___ / ___ / _____

Index Date ___ / ___ / _____

CANCER HISTORY

1. Subject's History of Primary Cancer **from beginning of chart up to index date**:

0=No
1=Yes
9=Unknown

		Yes/No:	Date of Dx:
A.	Breast	_____	___/___/_____
B.	Endometrial	_____	___/___/_____
C.	Colorectal	_____	___/___/_____
D.	Ovarian	_____	___/___/_____
E.	Cervical	_____	___/___/_____
F.	Other: site: _____ code: _____	_____	___/___/_____
	site: _____ code: _____	_____	___/___/_____

2. Family History of Cancer **from beginning of chart up to index date**:

0=No
1=Yes
9=Unknown

	Relative:	Rel. Code:	Cancer:	Cancer Code:	Age at Dx:
A.	_____	_____	_____	_____	_____
B.	_____	_____	_____	_____	_____
C.	_____	_____	_____	_____	_____
D.	_____	_____	_____	_____	_____
E.	_____	_____	_____	_____	_____
F.	_____	_____	_____	_____	_____
G.	_____	_____	_____	_____	_____
H.	_____	_____	_____	_____	_____

Revised 10-15-99
C. Spoutz

LIFESTYLE HISTORY

1. Smoking Status **starting with beginning of chart up to index date**:

0=No
1=Yes
9=Unknown

Date	Status: 1=Current Smoker 2=Past Smoker 3=Never Smoker	Packs/Day*	# of Years at this Packs/Day	If **Past Smoker**, Calendar Year Quit
___/___/_____				
___/___/_____				
___/___/_____				

*Cigarettes/day	Packs/day
1 – 5	0.25
6 – 10	0.50
11 – 15	0.75
16 – 20	1.0

2. Occupational History **within 10 years of index date**:

0=No
1=Yes
9=Unknown

Date	Name of Occupation	Years in Occupation
___/___/_____		
___/___/_____		
___/___/_____		

IF INCOMPLETE FOLLOW-UP:

1. Telephone numbers: Home: (____) _____ Work: (____) _____

   Emergency: (____) _____

2. Current address: Street Address _____

   City, State, Zip Code _____

3. Address **at index date**, if different: _____ Date: ___ / ___ / _____

   _____

4. Previous address, if different: _____ Date: ___ / ___ / _____

   _____

5. Spouse's employer: Name _____ Phone #: (____) _____

   City, State _____

6. Name and address of next-of-kin: _____

   _____

   _____

   Relationship:
   1. Current spouse
   2. Former spouse
   3. Offspring
   4. Parent
   5. Sibling
   6. Other, specify _____

7. Date of last physician visit or hospital admission: ___ / ___ / _____

8. Name of primary care physician: _____

9. Location of primary care physician: _____

BENIGN BREAST DISEASE MOLECULAR ANALYSIS FORM – FISH MARKERS SCORING SHEET Form FISHX18 MARKERS-043099 RevA

Path Number S - Date / / Initials Page Of

A X Block Slide Lesion Code AREA . X . TO . X .

0	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
1	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
2	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
3	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
4	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

A 1 8

0	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
1	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
2	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
3	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
4	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

B X Block Slide Lesion Code AREA: . X . TO . X .

0	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
1	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
2	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
3	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
4	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

B 1 8

0	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
1	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
2	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
3	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
4	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

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BENIGN BREAST DISEASE MOLECULAR ANALYSIS FORM – FISH MARKERS SCORING SHEET Form FISH17H2 MARKERS-043099 RevA

Path Number S - Date / / Initials Page Of

A17 Block Slide Lesion Code AREA . X . TO . X .

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APPENDIX D.

Abstracts

Title:

Ethnicity, stage of detection of breast cancer, and screening mammography in a health maintenance organization.

Abstract:

In a cohort of 886 women ascertained from an HMO and diagnosed with breast cancer from 1986-1996, crude 5 year survival for European American women (EA) was better than that for African American (AA) women (OR=1.6; 95%CI 1.1-2.2), with AA women diagnosed at a later stage. We hypothesized that the ethnic difference in stage at diagnosis could have been a result of differential use of screening mammography, although in this setting mammography is a covered benefit and strongly emphasized among the health plan physicians. To investigate this theory, we obtained information from automated data and medical records on the use of screening mammography during the three years prior to diagnosis. Only women who were continuously enrolled in the HMO during this time period were eligible. The women were classified into two age groups, 40-49 yrs. (n=141) and 50+ yrs. (n=295), based on age differences in screening guidelines.

Of the 436 women in the study, 28.9% were AA. Young AA women were diagnosed with stages II-IV (65.9%) more frequently than young EA women (47.0%). This difference was much less striking among women 50+ years.

In both age groups, AA women were significantly more likely than their EA counterparts to have not received a screening mammogram (73.2% vs. 40% for younger and 61.2% vs. 31.0% for older women). However, among women 40-49, AA ethnicity was strongly associated with later stage at diagnosis even after adjustment for screening (adjusted OR=2.8; 95%CI 1.2-6.8). Our data suggest that something other than mammography use (e.g. ethnic difference in breast tissue density and therefore mammography efficacy or ethnic difference in tumor aggressiveness), is related to stage at breast cancer diagnosis in young AA women.

Breast cancer incidence among a cohort of women with benign breast disease. AC Blount, U Raju, J Abrams, M Jankowski, SD Nathanson, SR Wolman, MJ Worsham, CC Johnson. Josephine Ford Cancer Center, Henry Ford Health System, Detroit, MI.

The risk of developing breast cancer has been reported to be increased among women with a history of benign breast disease (BBD). A cohort of women diagnosed with BBD from 1981 – 1994 was established to investigate this relationship in a large health care system. Women were eligible for entry with an initial index BBD biopsy performed during this time period. A diagnosis of breast cancer prior, concurrent or within 6 months of the index BBD biopsy ruled women ineligible for the cohort. The archived pathology reports of all breast biopsies were retrieved and reviewed by an expert breast pathologist to identify specimens containing only BBD lesions. The slides were microscopically reviewed for confirmation of the diagnosis utilizing a universal diagnostic terminology system. All cohort members were followed from their index BBD biopsy for the subsequent occurrence of breast cancer. During cohort establishment, 5254 women were found to be eligible and 116 ineligible. Slide review revealed the lesions were primarily proliferative (65%), with 30% non-proliferative, and 4% atypical ductal or lobular hyperplastic. The cohort yielded 167 cases of breast cancer detected through July 1999. With 48,201 person-years of follow-up, the average incidence rate was 346.5 per 100,000 (95% confidence interval [CI], 295.9 – 400.8), ranging from 298.3 (95% CI, 148.9 – 534.0) in the 1981 cohort year to 530.8 in 1994 (95% CI, 254.8 – 976.6). In comparison to 1991 – 1995 SEER rates of 353.8 nationally and 363.6 per 100,000 for the metropolitan Detroit area among women aged 50 and older, breast cancer incidence in this BBD cohort does not appear to differ from the general population.

USING GUIDED FOCUS GROUPS IN BREAST CANCER RESEARCH

Authors: Ford, M.E.; Hill, D.; Worsham, J.M.; Johnson, C.C.; Wolman, S.

Objective: To describe the results of two age-specific guided focus groups held with African American women to evaluate a breast cancer risk factor survey.

Methodology: A health system patient database was used to identify African American women aged 18 to 50 years (focus group one) and aged 50 years or older (focus group two). From these listings, 15 women were randomly selected, called, and invited to each focus group. Eligible and interested women received a mailed confirmation of their focus group and a reminder call. Each 2-hour focus group was videotaped.

Results: The women in the younger age group (n=12) stated that the rationale for the item on race/ethnicity was not clear, the relevance between parent's country of origin and breast cancer risk was not clear, and it was difficult to remember the number of menstrual periods they had had in previous decades. The women in the older age group (n=9) stated that in the past, their doctors did not name their medications. The meaning of several terms, such as "demographics," was not clear, and family medical history was often unknown. Women in both age groups stated that it was difficult to recall previous average weight, alcohol consumption, and level of physical activity, and that the sports listed were not culturally appropriate.

Conclusion: The results show that questionnaire items developed in the general population may not be appropriate for African American women.

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Developing a culturally appropriate breast cancer risk factor survey for African American women. Ford ME, Hill D, Worsham MJ, and Johnson, CC. *Josephine Ford Cancer Center, Henry Ford Health System, Detroit, MI 48202*

The purpose of this study was to develop a culturally appropriate breast cancer risk factor survey. Guided focus groups were conducted using items compiled from standardized surveys on breast cancer risk factors. The first focus group (n=12) was held with African American women aged 18-50 years randomly selected from the Henry Ford Health System patient population. A second focus group was held with nine randomly selected African American women aged 50+ years. Each two-hour focus group was videotaped. The women in the younger age group stated that the rationale for the item on race/ethnicity was not clear, the relevance between parent's country of origin and breast cancer risk was not clear, and that it was difficult to remember the number of menstrual periods they had had in previous decades. In the younger age group, breast cancer risk factors cited included heredity, smoking, underwire brassieres, chemical exposure, breast density, weight, drug use, and lack of estrogen exposure. The women in the older age group stated that in the past, their doctors did not name their medications or describe the full extent of their medical conditions. The meaning of several terms, such as demographics, was not clear, and family medical history was often unknown. In the older age group, breast cancer risk factors cited included heredity, hormone replacement therapy, diet, lack of breast self-exams and mammography, and estrogen exposure. Women in both age groups stated that it was difficult to recall previous average weight, alcohol consumption, and level of physical activity, and that the sports listed were not culturally appropriate. The results show that questionnaire items developed in the general population may not be appropriate for African American women, and that education about breast cancer risk factors is needed for this population.

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Incidence rates for breast cancer among women with benign breast disease.
CC Johnson, AC Blount , U Raju , J Abrams, SR Wolman, MJ Worsham.
Josephine Ford Cancer Center, Henry Ford Health System, Detroit MI.

Women with benign breast disease (BBD) have been shown to be at higher risk for breast cancer. A cohort of women with (BBD) from 1981-1989 in a large health system was ascertained. Hard copy records of all pathology files were reviewed and reports of breast biopsies pulled. These reports were reviewed by a pathologist specializing in breast lesions and classified as BBD versus other categories. Women with a concurrent or past history of breast cancer were excluded from the cohort. Women with a diagnosis of breast cancer within the six months following biopsy were also excluded.

All members of the cohort were (n=2263) followed for the occurrence of breast cancer through 1997. Follow-up commenced with the first biopsy classified as BBD. One hundred thirty one cases were identified over 21,317 person-years of follow up. The average incidence rate per year was 615 per 100,000 (95% confidence interval of 518-729). This compares to a SEER rate of 350.2 per 100,000 for women ≥ 50 years from 1990-94.

The incidence rates for breast cancer in this BBD cohort appear to be higher than those found in the same metropolitan area or as reported by SEER for the general population. Further analyses will stratify rates by race, age, and histologic type.

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Ethnicity and Survival from Lung Cancer in a Managed Care Organization.
Ulcickas Yood M, Blount A Coates R, Lamerato L, Abrams J, , Johnson CC

Studies indicate African Americans (AA) with lung cancer have poorer survival than non-AA We measured lung cancer survival among members of a Detroit area health maintenance organization who were served by physicians in a large multispeciality group practice. In this setting, many potential barriers related to insurance are removed, and diagnosis and treatment are relatively standardized. All lung cancer cases diagnosed from 1/86-12/96 among HAP members continuously enrolled for at least one year formed the cohort. Baseline data included race, date of birth, sex, marital status, and stage. Address was geocoded to census block group to obtain an estimate of median household income.

The cohort consisted of 827 patients, 280 AA and 547 non-AA. Mean ages and stage at diagnosis were similar. Median income was substantially different comparing AA ($18,200) and non-AA ($35,600). Overall, AA had poorer survival compared to non-AA (hazard ratio HR=1.20, 95%CI 1.02-1.42). Adjusting for income, the HR decreased to 1.05 (95%CI 0.85-1.31). Adjusting for stage, income, age, sex and marital status, the RR was 1.00 (95% CI of 0.80-1.27).

In a setting that removes a number of health care barriers and potential treatment differences, and after adjustment for stage and other socio-demographic variables, the survival difference between AA and non-AA was eliminated.

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Intraobserver Reliability in Classifying Breast Lesions in a Cohort of Women with Benign Breast Disease. Abrams J, Raju U, Worsham MJ, Johnson CC, Ulcickas Yood M, Wolman SR. *Josephine Ford Cancer Center, Henry Ford Health System, Detroit MI.*

We identified a cohort of women with benign breast disease diagnosed by breast biposy during the years 1981 through 1994. The study pathologist reviewed histology slides of breast biopsies to identify lesions using a classification based on risk categories for invasive carcinoma defined by Page and Dupont. A 10% random sample of slides, N=74, from years 1981 through 1983 was independently reviewed a second time by the same pathologist who was blinded at both readings to the identity of the patient.

Lesions with no increased risk included simple apocrine metaplasia, cysts, duct ectasia, mastitis, fibrosis, squamous metaplasia. Concordance on the two readings ranged from 85% for simple apocrine metaplasia to 99% for squamous metaplasia. Average agreement was 91%. Kappa statistics indicated significantly greater than chance agreement ($p<.001$) for all lesions but fibrosis. Lesions with slightly increased risk included moderate to florid adenosis (both simple and sclerosing), moderate to florid hyperplasia, and papillomas. Fibroadenomas, apocrine adenosis and radial scars are also regarded as proliferative lesions, i.e. having slightly increased risk, for the purpose of this study. Concordance ranged from 93% for simple adenosis and hyperplasia to 99% for apocrine hyperplasia with a mean of 96%. All kappa statistics indicated significantly more than chance agreement, $p<.001$. Lesions with moderately increased risk are atypical ductal hyperplasia (ADH) and atypical lobular hyperplasia (ALH). One case of ADH and no cases of ALH were found and the pathologist agreed at both readings. No high-risk lesions, i.e. ductal or lobular carcinoma in situ were found. We conclude that a trained breast pathologist can reliably classify lesions of different risk categories.

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Ethnicity, stage of detection of breast cancer, and screening mammography in a health maintenance organization. CC Johnson, U Bawle, ME Ulcickas Yood, Henry Ford Health System, Detroit MI 48202

In a cohort of 886 women ascertained from a health maintenance organization and diagnosed with breast cancer from 1986-1996, we found that crude 5 year survival for European American women (EA) was better than that for African American (AA) women (OR=1.6; 95%CI 1.1-2.2). AA women were diagnosed at a later stage, and the survival difference disappeared after adjusting for stage along with several demographic variables. We hypothesized that the ethnic difference in stage at diagnosis could have been a result of differential use of screening mammography as such differences have been found in other studies, although in this setting mammography is a covered benefit and strongly emphasized among the health plan physicians. To investigate this theory, we obtained information from automated data and medical records on the use of screening mammography during the three years prior to diagnosis. Only women who were continuously enrolled in the HMO during this time period were eligible. The women were classified into two age groups, 40-49 yrs. (n=141) and 50+ yrs. (n=295), based on age differences in screening guidelines. Of the 436 women in the study, 28.9% were AA. AA women were found to have lower income than EAs, and older AA women were less likely to be married. Young AA women were diagnosed with stages II-IV (65.9%) more frequently than young EA women (47.0%). This difference was much less striking among women 50+ years. Late stage disease was associated with shorter duration of HMO membership (OR=1.3, 95% CI 0.6-2.5). In both age groups, AA women were significantly more likely than their EA counterparts to have not received a screening mammogram (73.2% vs. 40% for younger and 61.2% vs. 31.0% for older women). However, among women 40-49, AA ethnicity was strongly associated with later stage at diagnosis even after adjustment for screening (adjusted OR=2.8; 95%CI 1.2-6.8). Our data suggest that something other than mammography use (e.g. ethnic difference in breast tissue density and therefore mammography efficacy or ethnic difference in tumor aggressiveness), is related to stage at breast cancer diagnosis in young AA women.

APPENDIX E.

Selected Papers

Patterns and Characteristics of Repeat Mammography among Women 50 Years and Older[1]

Marianne Ulcickas Yood,[2] Bruce D. McCarthy, Nancy C. Lee, Gordon Jacobsen, and Christine Cole Johnson

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Abstract

Whereas efforts encouraging women to obtain initial mammograms are laudable, the importance of returning for subsequent routine mammograms cannot be minimized. The purpose of this study was to measure the timing, patterns, and characteristics of repeat screening mammography over time in a defined population of health maintenance organization members for whom mammography was a fully covered benefit. We identified all women ages 50–74 years who were enrolled in a southeastern Michigan health maintenance organization, assigned to a large medical group, and received at least one screening mammogram with a normal result between January 1, 1989 and December 31, 1996. Using administrative and radiology data, we calculated the proportion of women who received a subsequent mammogram within 2 years and the time to subsequent screening, both overall and stratified by demographic characteristics. We also examined screening patterns over a 5-year period. Of the 8749 women included in this study, 66.0% [95% confidence interval (CI), 65.0–67.0%] were subsequently screened within 2 years. We found slightly higher rates among Caucasians and married women. The proportion of women who received repeat mammography increased with estimated household income [9.5% difference between the highest and lowest categories (95% CI, 6.5–12.5%)]. The median time to subsequent screening was 17.7 months, and the probability of repeat screening was higher for women whose initial mammogram was between January 1992 and December 1994 compared to those receiving an initial mammogram between January 1989 and December 1991 (9.6% difference; 95% CI, 7.5–11.7%). Repeat mammography has improved over time; however, socioeconomic status could contribute to longer-than-intended intervals between screening when translated into real-world clinical practice. In a setting where most physicians recommended annual screening, we found that the median time to subsequent screening was delayed by 6 months. If annual mammography is the goal, recommendations should be made with the understanding of how the timing of repeat screening occurs in clinical practice.

Introduction

The United States Preventive Services Task Force recommends routine screening for breast cancer (mammography alone or in combination with clinical breast examination) every 1–2 years for women ages 50–69 years (1), and the American Cancer Society recommends annual screening for women in this age group (2). In the clinical setting, although physicians and patients may try to adhere to specific guidelines, subsequent screening usually takes place within a window around that targeted goal. Information about the timing of repeat screening can be used to create recommendations that achieve the clinical goal and acknowledge that most subsequent screening will not take place strictly within the guidelines. Furthermore, understanding whether certain subgroups are less likely to receive timely repeat screening, particularly in a setting where the cost of screening is not a barrier to a woman or her physician, could facilitate the development of implementation strategies. To our knowledge, no study has examined the timing of repeat mammography in a multiethnic population. The purpose of this study is to measure the patterns and characteristics of repeat screening mammography over time in a defined population of HMO[3] members for whom the mammography guideline frequency was every 1–2 years and physicians recommended annual mammography.

Materials and Methods

We used radiology, billing, and other administrative data to identify a cohort of female HMO members who had undergone at least one screening mammogram. We then used these data to describe and compare the patterns and characteristics of repeat screening (after the initial screening mammogram) in this cohort.

Setting

HAP, the largest HMO in Michigan, has approximately 525,000 members. HAP has a network of 46 medical centers

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[1] Supported by a contract between the Office of Managed Care, the Centers for Disease Control and Prevention, and the American Association of Health Plans and Henry Ford Health System, Task Order #0957-011.

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[3] The abbreviations used are: HMO, health maintenance organization; HAP, Health Alliance Plan; HFMG, Henry Ford Medical Group; CI, confidence interval.

and 2,100 physicians associated with 18 hospitals. Approximately 57% of HAP members receive their care from physicians in the HFMG. Conversely, HAP members represent approximately 50% of the patients cared for by HFMG physicians.

The HFMG is a large, multispecialty group practice that consists of a hospital-based ambulatory care clinic in a large urban teaching hospital in Detroit (Henry Ford Hospital) and 26 satellite ambulatory care centers throughout southeastern Michigan. The hospital-based clinic and ambulatory sites are divided into six geographic regions for administrative purposes. We obtained the study population (see below) from women who were members of HAP and received at least one mammogram while under the care of a HFMG physician during the study period. Among the six regions in the HFMG, one region has a semiautonomous administrative, billing, and database structure; we excluded women assigned to this region.

Collection of Mammogram Data

All information about receipt of mammography came from two sources: (*a*) the HFMG radiology database; and (*b*) the HAP claims database (which records any patient billing activity outside HFMG).

HFMG Radiology Database. Mammography data from January 1, 1989 through May 30, 1992 were collected in the HFMG Department of Radiology, using a semistructured format. When the radiologists interpreted the film, they coded "track" in the database for all mammograms that required further follow-up. These "tracked" mammograms included screening mammograms that had an abnormal result and all diagnostic mammograms, regardless of the result. In this radiology database, the reason for the mammogram and the interpretation were recorded as free text.

Trained medical record abstractors used a structured abstracting form and reviewed the mammogram reports for all films classified as "track" during the study period. Using this information, we classified tracked mammograms as screening or diagnostic. Repeat abstraction of a sample of the reports showed that this process was highly reliable. Therefore, all screening mammograms during this time could be identified.

On June 1, 1992, the HFMG radiologists began interpreting and recording mammogram data in a highly structured format that included categorizing the indication for the mammograms, thereby providing easy identification of screening mammograms.

HAP Claims Data. We used HAP claims data to capture mammograms that occurred outside the HFMG. From these data, we could identify the location and dates of the mammogram; however, it was not possible to separate screening mammograms from nonscreening mammograms.

Identification of Study Cohort

We identified all women ages 50–74 years who were enrolled in HAP between January 1, 1989 and December 31, 1996 and who received at least one screening mammogram with a normal result at a HFMG site during the study period. For women who received more than one mammogram at a HFMG site within the study period, we randomly selected an index mammogram (reference mammogram from which subsequent screening was measured). We then limited the cohort to women who were enrolled continuously in HAP for at least 2 years after the index mammogram (to provide sufficient time for follow-up of subsequent screening) and who received mammography as a fully covered benefit. If a woman had two distinct enrollment intervals during the study period, we chose the longest continuous interval for the study. We excluded women who had only received mammograms outside the HFMG because we could not determine whether any of these mammograms were (as required for inclusion) for screening purposes.

For each member of the study population, we obtained race, marital status, date of birth, and zip code from the HFMG master patient index. This database contains information on all patients cared for by physicians in the HFMG.

Classification of Subsequent Mammograms

To identify subsequent mammogram patterns, any mammogram that occurred at least 9 months after the index screening mammogram was considered subsequent screening in this study. We used this classification scheme for all repeat mammograms, regardless of whether the subsequent mammogram was coded as screening in the database. This approach was selected for two reasons: (*a*) data on whether a mammogram was for screening or diagnostic purposes was not available from the HAP claims data (*i.e.,* mammograms received outside HFMG); and (*b*) a woman who had followed-up appropriately for annual screening but had an abnormality found on breast physical examination would have this follow-up mammogram coded as nonscreening (although the woman clearly followed-up with the screening process). We presumed that any mammograms received within 9 months after a screening mammogram were for nonscreening purposes and excluded these women from the analysis.

Statistical Analysis

Proportion of Women Subsequently Screened. To measure compliance with the United States Preventive Services Task Force screening guidelines, we calculated the proportion of women who received a subsequent mammogram within 2 years after the index screening mammogram. We also calculated these proportions and 95% CIs stratified by race (African American, Caucasian, and other), marital status (married or not married), age (in years; 50–54, 55–59, 60–64, and 65+), median household income based on zip code and United States census data (in dollars; 0–25,399, 25,400–38,099, and 38,100+), and timing of index mammogram (January 1989 through December 1991 and January 1992 through December 1994).

Subsequent Mammograms as a Function of Time. We used Kaplan-Meier estimates to measure the time from index mammogram to the subsequent mammogram. Women without a subsequent mammogram were censored at the end of the HAP enrollment period (for members who left the plan) or at the end of the study period (December 31, 1996), whichever came first. We stratified all analyses by race, marital status, age, median household income based on zip code and United States census data, and the timing of the index mammogram.

To measure the independent effect of race, marital status, age, income, and the timing of the index mammogram, we fit a multivariable proportional hazards model. We found no material differences between the crude and adjusted effect estimates; therefore, we present crude effect estimates in this study.

Subsequent Mammograms over a 5-Year Period. To measure the cumulative number of subsequent mammograms that occurred at least 9 months after the index mammogram over an extended period, we limited the population to women continuously enrolled in HAP for at least 5 years after the index mammogram.

Table 1 Frequency of repeat screening mammography by demographic characteristics (n = 8749 women)

Characteristic	Received subsequent screening within 2 years of index mammogram		
	n	%	Difference in percentages, compared to baseline (95% CI)[a]
Overall	5772	66.0	—
Race[b]			
Caucasian	4332	67.0	—
African American	1135	62.2	−4.8 (−7.3 to −2.3)
Other	115	64.6	2.4 (−4.7 to 9.5)
Age (yrs)			
50–54	1759	65.9	—
55–59	1358	67.2	1.3 (−1.4 to 4.0)
60–64	1181	66.8	0.9 (−1.9 to 3.7)
65+	1474	64.3	−1.6 (−4.3 to 1.1)
Married[c]			
Yes	4144	67.8	—
No	1538	61.9	−5.9 (−8.1 to −3.7)
Median income ($)[d]			
0–25,399	875	59.1	—
25,400–38,099	1518	64.4	5.3 (2.1–8.5)
38,100+	2051	68.6	9.5 (6.5–12.5)
Timing of index mammogram			
1/89–12/91	1884	59.8	—
1/92–12/94	3888	69.4	9.6 (7.5–11.7)

[a] Baseline category indicated by —.
[b] Race was unknown for 276 women.
[c] Marital status was unknown for 149 women.
[d] Income based on 1990 census data. Zip code of residence was unknown for 1919 women.

Results

Proportion of Women Subsequently Screened. We identified 9017 women who met the eligibility criteria for the study. From this group, we excluded 268 women because they received a second mammogram within 9 months of the index screening mammogram, leaving a final sample of 8749 women. The percentages of women who received a subsequent mammogram within 2 years by demographic characteristics are shown in Table 1. The overall percentage of women receiving subsequent mammograms within 2 years was 66.0% (95% CI, 65.0–67.0%). When stratified by demographic characteristics, we found that African American women and unmarried women were less likely to receive subsequent screening. In addition, as estimated median household income increased, the proportion of women with subsequent screening improved. The percentage of women that received subsequent mammograms within 2 years of the index mammogram was higher for those with an index mammogram between January 1992 and December 1994 compared with women who had an index mammogram between January 1989 and December 1991 (difference = 9.6%; 95% CI, 7.5–11.7%).

Subsequent Screening as a Function of Time. Overall, the median time to subsequent screening was 17.7 months. Fig. 1 illustrates the probability of repeat mammography over time for all women in the study (n = 8749; *i.e.,* those continuously enrolled for at least 2 years). Fig. 1 shows that after excluding those few women with a subsequent mammogram within 9 months, 66.0% of the women received a subsequent mammogram at least 9 months after but within 2 years of the index mammogram. The proportion of women receiving subsequent screening increases steadily up to 36 months, at which time the rate of increase levels off and plateaus at around 88% in 5 years. Fig. 1 also illustrates the effect of timing of the index mammogram, with higher rates of subsequent mammography in the group of women initially screened between 1992 and 1994. The pattern of repeat screening (*i.e.,* the shape of the curve) when the analyses were stratified by demographic characteristics was similar to those seen overall.

Results for Women Continuously Enrolled for at Least 5 Years. When we limited the study population to the 2248 women enrolled continuously in HAP for at least 5 years after the index screening mammogram, we found that 83.3% of women received at least one subsequent mammogram (Table 2). The proportion of women with at least four mammograms was 19.2%, and <1% had at least five mammograms.

Discussion

During the study period, the official guidelines for these HMO members recommended mammography every 1–2 years. However, we conducted an informal survey of 50 primary care physicians serving these members, and we found that the overwhelming majority of doctors (96%) have recommended annual mammography for their patients in this age group since 1990. The target of annual mammography reported by physicians in our health system parallels that of other physician surveys (3–6). Despite the goal of annual screening, in this study we found that among women 50–74 years of age with a normal screening mammogram, 66% received a subsequent mammogram within 2 years of the initial screen, and 88% received a subsequent mammogram within 5 years. The median time to subsequent screening was almost 1.5 years.

In terms of proportions receiving repeat mammography, our results are similar to those from a small study (7) in which 70% of women reported subsequent screening 21–27 months after their first mammogram and from another study in which 73% received repeat mammography within 18 months (8). Other investigators conducted a survey and found that in a community setting, 41% of women had two or more mammograms within 5 years (9). In contrast, one study in a low-income population in Los Angeles (10) found that only 25% of women received subsequent screening within 21 months, and another study in Illinois found that 33% of low-income women received a subsequent mammogram within 3 years (11). However, unlike our study, none of these studies reported the patterns of subsequent mammography as a function of time. Timing was categorized in the Los Angeles study (10); interestingly, the average time to subsequent mammography was 11 months, less than the minimal recommended interval (1, 2). However, these results may be explained by the fact that the investigators did not attempt to exclude mammograms that were performed as follow-ups to abnormal screening results.

We found small differences in the proportion of women receiving subsequent screening for some demographic variables. The proportion of African American women subsequently screened was nearly 5% lower than that for Caucasians, and the proportion for unmarried women was 6% lower than that for married women. Because women in our study were enrolled in a HMO and mammography was a fully covered benefit for these women, barriers related to economic access should theoretically be eliminated in this population. The charge for screening mammography has been implicated as a key reason why women do not undergo screening (12). However, we did find that income, measured indirectly by zip code, had an effect on repeat mammography, with the highest income category showing percentages of subsequent screening almost 10% higher than the lowest category. The effect of income seen in our study is consistent with results from other studies of

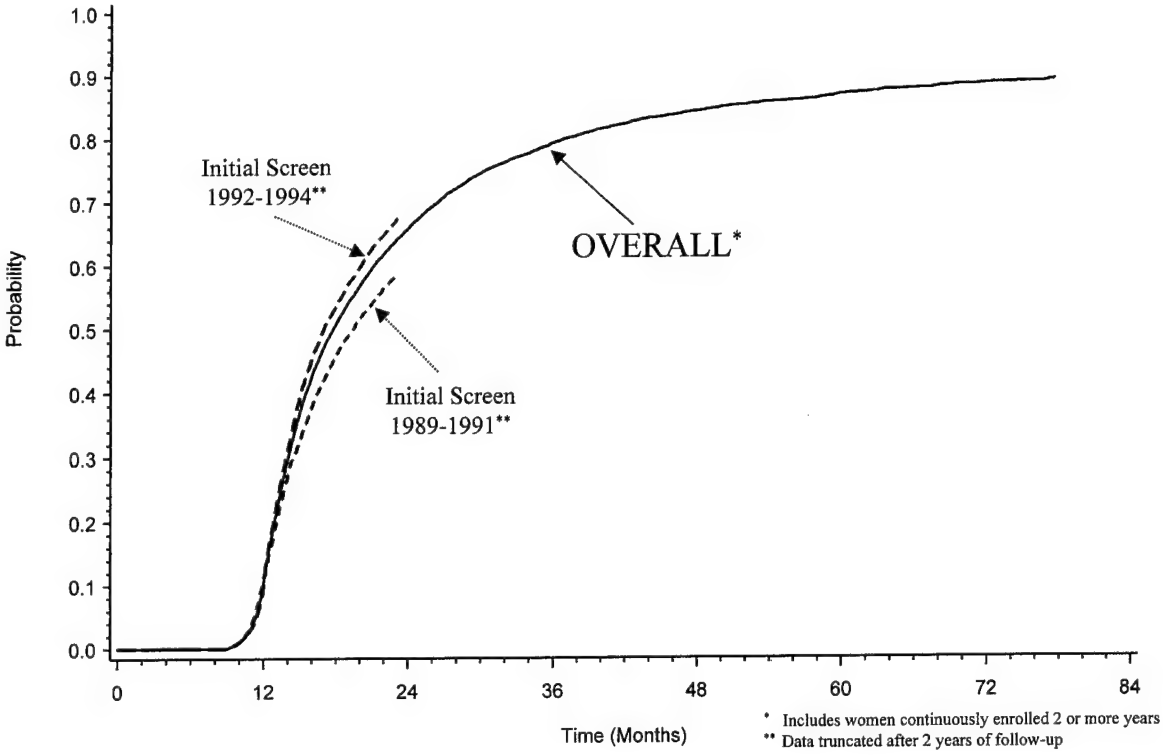

Fig. 1. Probability of repeat screening over time. The probability of repeat screening of women initially screened from 1989–1991 is compared to the probability of repeat screening of women initially screened from 1992–1994. *Solid line*, probability in overall study population.

Table 2 Frequency of subsequent mammograms during 5 years of follow-up, limited to women enrolled continuously for at least 5 years after index mammogram

Cumulative no. of subsequent screening mammograms[a]	No. subsequently screened	% of total (n = 2248)
>5	19	0.8
≥4	432	19.2
≥3	940	41.8
≥2	1419	63.1
≥1	1874	83.3

[a] This category includes only mammograms received at least 9 months after the index mammogram.

repeat (10, 11) or recent (within the past year; Refs. 12 and 13) mammography and even follow-up of abnormal mammograms (14) that show lower rates in low-income populations. The unique contribution of our study is that we were able to examine this effect in a multiethnic population of HMO members. Our results indicate that eliminating other barriers, besides the charge for screening mammograms, plays a role, and health systems need to target low-income women and provide the education necessary to make mammography a habit.

Cross-sectional data from the National Health Interview Survey indicates that the proportion of women who reported receiving mammography within the past year has improved over time (12, 13). In fact, among women 50 years and older, the proportion who had a mammogram in the last year rose from 27.4% in 1987 to 60.6% in 1994 (13). Our prospective results show that the secular trend for recent mammography may also translate to repeat mammography, with an increase of almost 10% comparing 1989–1991 to 1992–1994. We formed these secular categories solely to ensure appropriate and equivalent follow-up data for each time period. However, we can speculate that the improvement over time seen in our system may be due in part to various initiatives within the health system that emphasized the importance of mammography. In 1992, some clinics began measuring and feeding back mammography rates to physicians and emphasizing the importance of a population-based perspective that included outreach strategies for women overdue for screening as well as improvements in office-based strategies to increase screening (15). At this time, some groups began experimenting with developing and implementing new processes for offering mammography (including identification of women due for a mammogram and progress-related feedback) executed completely by nonphysicians (16). Because clinicians and administrators mounted these various efforts at the clinic level rather than the system level, we are not able to directly correlate our findings in this study with any specific initiatives. However, these activities may have prompted physicians and other office staff to focus on encouraging women to receive regular screening.

Whereas a major strength of this study is the setting that removes variation in insurance benefits and provides a relatively standard medical practice, these findings may not be applicable in other populations. In addition, we could only indirectly measure socioeconomic status through the use of zip code information. Another limitation of this study is that we did not have precise data on the indication for all repeat mammograms; instead, we used a time window to separate screening from diagnostic repeat mammograms.

In summary, in a setting in which physicians aimed for annual mammography, we found that certain groups of women were less likely to obtain repeat mammography according to targeted goals. As a result, outreach programs may need to be tailored to improve the adherence among subgroups of women. We also found that in a setting in which physicians aimed for annual screening, the median time to subsequent screening was almost 18 months. This 6-month delay could be viewed as an absolute measure or as a proportion equal to half again the targeted screening interval. Whatever the optimal screening interval is determined to be, recommendations should be made with the understanding of how the timing of repeat screening occurs in clinical practice.

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Race and Differences in Breast Cancer Survival in a Managed Care Population

Marianne Ulcickas Yood, Christine Cole Johnson, Angela Blount, Judith Abrams, Eric Wolman, Bruce D. McCarthy, Usha Raju, David S. Nathanson, Maria Worsham, Sandra R. Wolman

Background: **African-American women with breast cancer have poorer survival than European-American women. After adjustment for socioeconomic variables, survival differences diminish but do not disappear, possibly because of residual differences in health care access, biology, or behavior. This study compared breast cancer survival in African-American and European-American women with similar health care access.** ***Methods:*** **We measured survival in women with breast cancer who are served by a large medical group and a metropolitan Detroit health maintenance organization where screening, diagnosis, treatment, and follow-up are based on standard practices and mammography is a covered benefit. We abstracted data on African-American and European-American women who had been diagnosed with breast cancer from January 1986 through April 1996 (n = 886) and followed these women for survival through April 1997 (137 deaths).** ***Results:*** **African-American women were diagnosed at a later stage than were European-American women. Median follow-up was 50 months. Five-year survival was 77% for African-American and 84% for European-American women. The crude hazard ratio for African-American women relative to European-American women was 1.6 (95% confidence interval [CI] = 1.1–2.2). Adjusting only for stage, the hazard ratio was 1.3 (95% CI = 0.9–1.9). Adjusting only for sociodemographic factors (age, marital status, and income), the hazard ratio was 1.2 (95% CI = 0.8–1.9). After adjusting for age, marital status, income, and stage, the hazard ratio was 1.0 (95% CI = 0.7–1.5).** ***Conclusion:*** **Among women with similar medical care access since before their diagnoses, we found ethnic differences in stage of breast cancer at diagnosis. Adjustment for this difference and for income, age, and marital status resulted in a negligible effect of race on survival. [J Natl Cancer Inst 1999;91: 1487–91]**

In the United States, survival for African-American women with breast cancer is inferior to that for European-American women *(1)*. The 1970s and 1980s marked a time of relatively stable rates of mortality among European-American women with breast cancer but of increasing rates for African-American women *(1)*. The decline in mortality observed in the early 1990s for European-American women with breast cancer was not observed in African-American women *(1,2)*. Poorer survival among African-Americans has been attributed to biologic characteristics of the tumor, advanced stage at diagnosis, lower socioeconomic status (SES), barriers to health care, diagnostic and treatment delays *(3,4)*, and a higher prevalence of comorbid conditions *(5,6)*. Although use of mammography by African-American women has been reported to lag behind use by Caucasian women *(7)*, research *(8)* indicates that this racial discrepancy is narrowing. However, it is too soon to see how increased use of mammography among African-American women will affect survival.

Most investigations *(9–11)* have found differences in tumor stage at disease presentation across ethnic groups. Use of multivariate models to control for biologic differences and sociodemographic characteristics has usually reduced but not eliminated the racial differential in survival *(6,12–15)*. Many investigators *(16–19)* have attributed the mortality differences primarily to racial disparity in SES, by way of its influence on diagnostic delays or even a lag in benefiting from medical advances *(20)*. Others *(6,9,10)* have perceived an important role for intrinsic differences in tumor aggressiveness.

We present analyses of breast cancer survival in a population of health maintenance organization (HMO) members where screening, diagnosis, treatment, and follow-up patterns are based on practice standards and are similar for all members of the population served within a large, multidisciplinary group practice. We selected this population to minimize heterogeneity in care delivery and to minimize financial barriers to health care.

Methods

Setting

The setting for this study was the Health Alliance Plan (HAP) HMO. HAP is located in southeastern Michigan and is the largest HMO in Michigan, with more than 450 000 members. Approximately 20% of these members are African-American, 53% are female, and 57% are cared for by physicians in the Henry Ford Medical Group (HFMG). Our study population was drawn from HAP members served by the HFMG. The HFMG is a large group practice that includes an urban medical center in Detroit with primary and specialty care clinics and 26 smaller clinics throughout urban and suburban southeastern Michigan.

The HFMG maintains a computerized tumor registry database accredited by the American College of Surgeons. Registry staff use a thorough case-finding system, including review of all pathology and cytology reports, as well as radiation and oncology consultations. The American Joint Commission on Cancer staging system *(21)*—called "TNM staging"—is used to determine the stage of disease by evaluating tumor size, extent of invasion, microscopic involvement of lymph nodes, and presence of metastases. HFMG registry staff link these data with Detroit area Surveillance, Epidemiology, and End Results (SEER)[1] Program records and conduct annual follow-up for vital status and recurrence. Follow-up information is complete for 94% of the women in the tumor registry.

Ascertainment of Case Patients

By use of the HFMG cancer registry, we identified all African-American and European-American women with incident breast cancer first diagnosed from January 1986 through April 1996. To minimize heterogeneity in clinical practice and access to care just before diagnosis, we limited the study population to women continuously enrolled in HAP for at least 1 year before diagnosis and assigned to a primary care physician within the HFMG at the time of diagnosis. We defined continuous enrollment as no

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See "Notes" following "References."

more than a 60-day gap in coverage according to membership files.

Outcome Data

We used several sources to identify follow-up data. First, we obtained vital status, date of death (if applicable), and date last known alive from the HFMG tumor registry. Next, for those women thought to be alive, we used HFMG administrative billing data to obtain information about hospitalizations and outpatient visits from January 1986 through April 1997. We used the billing data to update the tumor registry date where appropriate.

Identification of Related Variables

By use of the tumor registry, we obtained information on tumor characteristics, date of diagnosis, pathologic stage at diagnosis (including tumor size), and demographic factors (race, date of birth, and marital status). The demographic variables were primarily obtained from a self-administered questionnaire completed by new patients. We geocoded addresses from billing files into census block groups. We estimated household income for each woman by use of block group level median household income from the 1990 census data. Information about duration of HAP membership and mammography benefits was downloaded from the HMO membership files.

Statistical Methods

To evaluate the association between stage and race, we fit a multinomial logistic model in which we included pathologic stage (0, I, II, III, or IV) as the dependent variable and race (European-American or African-American) as the independent variable. We compared survival between African-American and European-American women by use of the hazard ratio and 95% confidence interval (CI) calculated from Cox proportional hazards models. In the model, we included marital status (unmarried or married), age at diagnosis (<55 years or ≥55 years [corresponding to the mean of this dataset]), estimated household income (<$35 000 or ≥$35 000 [likewise, the mean]), and pathologic stage (0, I, II, III, or IV) as indicator terms. Age of less than 55 years, married, income below $35 000, and stage II disease were the reference categories used in the adjusted model (because they included the largest number of women). All variables included in the model were chosen on the basis of known relationships with both breast cancer survival and race (i.e., as potential confounders). The assumption of proportional hazards was assessed graphically and by use of Schoenfeld's χ^2 goodness-of-fit procedures *(22)*.

We considered the possibility that our method of updating the tumor registry's "date last known alive" with visit data would bias our estimates of survival if one ethnic group were more likely to have contact with the HFMG following diagnosis. Therefore, we conducted the analysis twice: First, we included only tumor registry follow-up dates; second, we used the billing data in addition. Differences between the two approaches were found to be negligible; therefore, analyses including the updated data are used in this report.

Results

We identified 1321 African-American and European-American women members of HAP who were diagnosed with breast cancer from January 1986 through April 1996 and for whom mammography was a fully covered benefit. From this group, we excluded 161 women because they were not assigned to HFMG physicians at the time of diagnosis and an additional 274 women because they were not continuously enrolled in HAP for 1 year before diagnosis, for a final sample of 886 women. The proportion of African-Americans (30%) was the same among the women excluded and the study group.

The median follow-up time was 50 months overall and was similar for African-American (49 months) and European-American (50 months) women who were alive at the end of follow-up. A total of 137 deaths occurred during the study period. Table 1 shows the baseline demographic and tumor-specific characteristics of the study population. The multinomial logistic model indicated that European-American women were more likely to have earlier stage disease at diagnosis than were African-American women. When we examined this issue more closely, European-Americans were more likely than African-Americans to have disease of an earlier stage (0 or I), with an absolute difference of 11% (95% CI = 3%–18%). Among women diagnosed with stage II disease (which includes cancers with and without lymph node involvement), we found no material difference between African-American and European-American women in the proportions with positive lymph nodes (difference = 5%; 95% CI = –6% to 17%).

The 5-year survival was 77% for African-Americans and 84% for European-Americans. The crude estimates by race are shown in Fig. 1. African-American women had poorer survival compared with European-American women (hazard ratio = 1.6; 95% CI = 1.1–2.2). Table 2 presents the hazard ratios adjusted for pathologic stage and sociodemographic factors, separately and in combination. When stage was added to the model, the hazard ratio decreased to 1.3 (95% CI = 0.9–1.9). Adjusting only for sociodemographic factors, the hazard ratio was re-

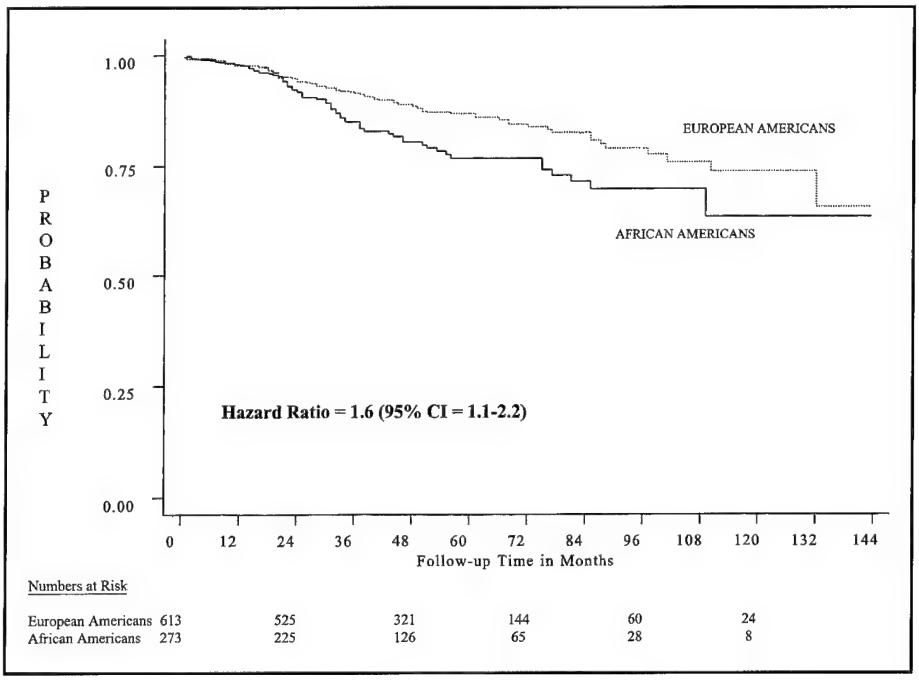

Fig. 1. Crude Kaplan–Meier survival estimates, by race. For the 886 African-American and European-American women with breast cancer who were seen at the Health Alliance Plan–Henry Ford Medical Group from January 1986 through April 1996, the cumulative survival proportion at 36 months of follow-up was 0.85 (95% confidence interval [CI] = 0.80–0.89) and 0.92 (95% CI = 0.89–0.94) for European-Americans; at 72 months, the cumulative survival was 0.77 (95% CI = 0.70–0.82) for African-Americans and 0.84 (95% CI = 0.80–0.87) for European-Americans; at 108 months, the cumulative survival was 0.70 (95% CI = 0.61–0.77) for African-Americans and 0.76 (95% CI = 0.68–0.82) for European-Americans. The table below the *x*-axis shows the numbers of patients at risk at representative time points. Symbols used: ------- = European-American; —— = African-American

duced to 1.2 (95% CI = 0.8–1.9). When we controlled for both stage and sociodemographics, the hazard ratio was reduced to 1.0 (95% CI = 0.7–1.5). The survival curves by race, adjusted for sociodemographic characteristics and stage, are shown in Fig. 2 and reflect this equivalent survival pattern. There was no evidence of violation of the proportional hazards assumption in the adjusted model.

Discussion

It is well-known that survival after breast cancer diagnosis is poorer for African-American women than for European-American women *(1–3,6,13–15,17,19)*. It is difficult to summarize the pertinent literature because no two studies are precisely comparable, and many papers are quoted differently by the authors who cite them. Nevertheless, some valid generalizations are relevant here. As we found, the difference in distribution of stage at detection has a major influence on differential African-American/European-American survival but does not fully explain it *(6,10–15)*.

By studying only HAP–HFMG patients, we eliminated the issue of lack of insurance coverage for screening and diagnostic services, a factor associated with both later stage at diagnosis and lower SES *(4,6,15,23)*. Even within this equal-coverage population, with its relative homogeneity of health care access and delivery, a large discrepancy in stage remains between African-American and European-American women (Table 1). Our study was not designed to investigate reasons for differences in stage at detection such as mammography use. However, two existing studies, both conducted in HAP–HFMG populations during approximately the same time period as this study, shed some light on this question. These studies measured, respectively, the proportion of women more than 50 years old who received mammography according to guidelines (relatively, 5.6% fewer African-American than European-American women) *(24)* and the proportion of women more than 50 years old with normal screening mammograms who were screened again within 2 years (relatively, 7.2% fewer African-American than European-American women) *(25)*. These small racial differences in mammography use among women in the same health care system as our sample have two implications: 1) The differences in mammography use are probably too small to explain the racial differences in stage at detection (relatively, 19% fewer African-American women with stage 0 or I disease; Tables 1 and 2) as implied above, uniform insurance coverage and clinical practices are not sufficient to equalize completely African-American and European-American women's use of breast cancer screening services.

Use of health care influences stage at diagnosis and the effectiveness of treatment *(4,11,23)*. The difficulty of obtaining data on populations with even approximate uniformity of care motivates our study. Its detailed results cannot be generalized to different populations or regions, but it constitutes an important addition to the body of work that greatly reduces the influence of race on survival by adjusting for stage and SES.

Wojcik et al. *(26)* eliminated the insurance factor by studying women cared for in the Department of Defense system, which also tries to provide equal access. The authors found that, among women with breast cancer, after adjustment for age and stage, European-American women had better survival than African-American women; however, Wojcik et al. did not control for income, a factor that varied by race in our sample of HMO members.

In our population, sociodemographic variables and stage, taken separately, had comparable confounding effects on the association between race and survival. As noted by Weiss et al. *(27)* and illustrated in the literature that we cite, SES is difficult to quantify and consists of a constellation of factors, although income plays a primary role. We know of one study besides our own that employs census data at the block group level *(28)* to improve the precision of SES estimates. Bassett and Krieger *(16)* do this by using six measures of SES other than income, and they adjust for age and stage. However, they did not study a sample with equivalent health care coverage. Both our study and that of Bassett and Krieger *(16)* come very close to eliminating race as an independent influence on survival.

The results of our study indicate that factors other than the ability to pay for services affect breast cancer survival. These factors may have some influence on stage at detection in particular. They include various beliefs about cancer risk and the usefulness of early detection, differences in the effects of various outreach and reminder strategies, differences in access mediated by transportation or the ability to get time off from work to keep appointments, obesity, comorbidities, and

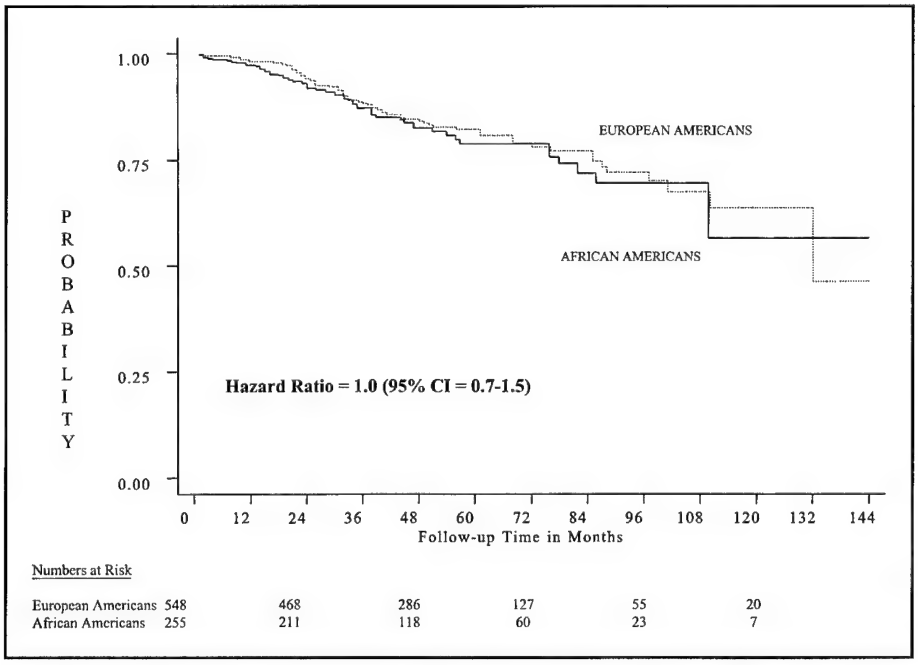

Fig. 2. Survival by race, adjusted for age, income, marital status, and stage. Adjusted Kaplan–Meier curves for 886 women with breast cancer seen at the Health Alliance Plan–Henry Ford Medical Group from January 1986 through April 1996. The table under the *x*-axis gives the numbers of patients at risk at representative time points. CI = confidence interval. Symbols used: ------- = European-American; —— = African-American.

Table 1. Baseline demographic and tumor characteristics*

	Value (95% CI)	
	African-American (n = 273)	European-American (n = 613)
Sociodemographics†		
Married	54% (48%–60%)	59% (65%–73%)
Mean age in y at diagnosis	55 (54–57)	56 (55–57)
Median household income ($1000)	26 (24–27)	44 (42–45)
Mean HMO enrollment before diagnosis, y	6.9 (6.3–7.5)	5.4 (5.1–5.7)
Tumor characteristics		
Stage‡		
∅	17% (13%–22%)	21% (17%–24%)
I	29% (24%–34%)	36% (32%–40%)
II	40% (34%–46%)	33% (29%–37%)
III	9% (5%–12%)	7% (5%–12%)
IV	5% (2%–8%)	3% (1%–4%)
Mean tumor size, cm	2.4 (2.1–2.6)	2.1 (2.0–2.3)

*CI = confidence interval; HMO = health maintenance organization.

†Marital status missing for five African-American and eight European-American women. Median household income missing for 13 African-American and 56 European-American women. Both marital status and median income missing for one European-American woman.

‡Stage according to the American Joint Commission on Cancer system *(21)*.

Table 2. Effect of demographic and tumor characteristics on survival estimates

Variables in model	Hazard ratio, African-American versus European-American	95% confidence interval
Race only	1.6	1.1–2.2
Race + stage*	1.3	0.9–1.9
Race + sociodemographic factors†	1.2	0.8–1.9
Race + stage + sociodemographic factors†	1.0	0.7–1.5

*Stage according to the American Joint Commission on Cancer system *(21)*.

†Age, marital status, and median household income.

differences in breast density that modify the effectiveness of mammograms *(4,11, 23,29–33)*.

A fundamental question for us, and for the related studies we cite, is whether African-American women have intrinsically more aggressive tumors than European-American women, thus affecting their survival either directly or by way of stage at detection because of more rapid progression. Our study did not incorporate estrogen receptor status or histologic tumor grade because they were often omitted from the HFMG tumor registry and, when available, had not been evaluated consistently.

The literature can be roughly divided into studies that find intrinsic differences in tumor aggressiveness (higher nuclear and histologic grade, S-phase fraction or mitotic index, and estrogen receptor negativity) to exercise a major influence on differential African-American/European-American survival *(6,9,10)*, and the greater number that find no positive evidence for this effect because they attribute a very limited influence to race after adjustment for stage and SES *(15–20)*. In a population with uniform health care coverage, we found that the residual influence of race after adjustment is negligible (hazard ratio = 1.0; 95% CI = 0.7–1.5). This result lends support to the view that the effect of an intrinsic difference in tumor biology (if any) must be small and exercised mainly through its influence on stage at diagnosis.

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NOTES

[1]*Editor's note:* SEER is a set of geographically defined, population-based, central cancer registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Registry data are submitted electronically without personal identifiers to the NCI on a biannual basis and the NCI makes the data available to the public for scientific research.

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APPENDIX F.

Budget Extension Request

DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY

FROM 4/1/99 THROUGH 3/31/00

PERSONNEL (Applicant Organization Only) NAME	ROLE ON PROJECT	TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents) SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Christine Cole Johnson	Principal Investigator	12	5	$0	$0	$0	$0
Jan Wells	Interviewer	12	10	$21,632	$2,163	$508	$2,671
					$0	$0	$0
				SUBTOTALS---------->	$2,163	$508	$2,671

CONSULTANT COSTS		
EQUIPMENT (Itemize)		
SUPPLIES (Itemize by category) Buccal Cell supply kits $3.20 per kit for 8,000 kits		$25,600
TRAVEL		
PATIENT CARE COSTS	INPATIENT	$0
	OUTPATIENT	$0
ALTERATIONS AND RENOVATIONS (Itemize by category)		$0
OTHER EXPENSES (Itemize by category)		
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$28,271**
CONSORTIUM/CONTRACTUAL COSTS DIRECT COSTS INDIRECT COSTS	TOTAL-->	390
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page) ------>		**$28,661**

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD (from page 4)	ADDITIONAL YEARS OF SUPPORT REQUESTED 2nd	3rd	4th	5th
PERSONNEL: *Salary & fringe benefits* *Applicant organization only*		$2,671	$0	$0	$0	$0
CONSULTANT COSTS		$0	$0	$0	$0	$0
EQUIPMENT		$0	$0	$0	$0	$0
SUPPLIES		$25,600	$0	$0	$0	$0
TRAVEL		$0	$0	$0	$0	$0
PATIENT COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES		$0	$0	$0	$0	$0
SUBTOTAL DIRECT COSTS		$28,271	$0	$0	$0	$0
CONSORTIUM/ CONTRACTUAL	DIRECT	$0	$0	$0	$0	$0
	INDIRECT	$390	$0	$0	$0	$0
TOTAL DIRECT COSTS		$28,661	$0	$0	$0	$0

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *(Item 8a)->* **$28,661**

From: Marsha Kelter
To: internet:det.amedd.army.mil:ann:cullen
Subject: DAMD17.96.1.6246

Dear Ann:

Dr. Christine Cole Johnson has requested a no cost extension on the above referenced grant. She is requesting that the work be concluded on 9/30/00 and the grant end on 10/31/00. Dr. Johnson's request has the full support of Research Administration, Henry Ford Health System. Assurances have been given by Dr. Johnson's staff that there are sufficient funds left in the grant for Dr. Johnson's required travel. A rebudgeting form has been requested for forwarding to you.

Sincerely,

Marsha Kelter, M.S.
Senior Grant/Contract Specialist
Research Administration CFP-1
Henry Ford Health System
2799 West Grand Blvd.
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